# Developing and Evaluating a Stepped Change Whole-University approach for Student Wellbeing and Mental Health: Feasibility study with embedded pilot RCT of a written strength-based low-intensity CBT intervention to enhance resiliency [ERUS] (Bounce Back)

**Trial Protocol Version 1.0 dated 05/06/2023**

**Funded by: UKRI – MRC Adolescence, Developing Mind and Mental Health scheme**


**Feasibility study with embedded pilot RCT of a written strength-based low-intensity CBT intervention to enhance resiliency (ERUS)**

**RESEARCH REFERENCE NUMBERS**

| | |
|---|---|
| **IRAS number:** | **Not applicable** |
| **ISRCTN:** | **18276230** |
| **Ethics application ID:** | **520569** |
| **Sponsor protocol number:** | **2022-23-28** |

**Table 1 PROTOCOL VERSION NUMBER AND DATE**

| Version | Date | Changes from previous version |
|---|---|---|
| **0.1** | **31/3/2022** | **Based on HRA template as advised by sponsor** |
| **0.2** | **15/8/2022** | **Protocol flow chart (Page 8)**<br>**Approved Ethics version** |
| **0.3** | **24/8/2022** | **Update to outcome inclusion/exclusion cut offs** |
| **1.0** | **05.06.2023** | **Key contacts update. Removal of committee member names. Addition of TikTok as a social media advertising avenue. Section 7.1.3 payment amounts clarified. Section 7.4 clarification of who is blinded and unblinded. Section 9 Adverse event reporting requirements changed in line with Exeter Clinical Trials Unit SOP and AE and SAE examples updated. SAE reporting flowchart updated. Section 10.2 Revised recruitment end date specified. Minor revisions, typing errors, layout and formatting updated throughout. GP letters removed and stand-alone documents created. SAE form removed as out of date (revised version available electronically on database). Changed reference to 3 month follow up to 12 weeks follow up.** |
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**Table 2 PROTOCOL AMENDMENTS**

| Amendment | Date | Changes from previous version | Date Authorised |
|---|---|---|---|
| **Protocol** | **15/8/22** | **Updated to ensure correct protocol – v2 to replace v1 dated 27/6/22 (Page 8)** | |
| **Outcome measures** | **24/8/22** | **Update to outcome inclusion/exclusion cut offs** | |
| **Non-substantial amendment 1 (CTU)**<br><br>**V3.0 Amendment (REC)** | **17.06.2023** | **Key contacts update. Removal of committee member names. Addition of TikTok as a social media advertising avenue. Section 7.1.3 payment amounts clarified. Section 7.4 clarification of who is blinded and unblinded. Section 9 Adverse event reporting requirements changed in line with Exeter Clinical Trials Unit SOP and AE and SAE examples updated. SAE reporting flowchart updated. Section 10.2 Revised recruitment end date specified. Minor revisions, typing errors, layout and formatting updated throughout. GP letters removed and stand-alone documents created. SAE form removed as out of date** | **20.06.2023** |

| | | | |
|---|---|---|---|
| | | **(revised version available electronically on database). Changed reference to 3 month follow up to 12 weeks follow up.**<br>**Update to outcome inclusion/exclusion cut offs** | |
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SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the trial in compliance with the approved protocol and will adhere to the principles outlined including clinical trial regulations, GCP guidelines, the Sponsor's SOPs, and other regulatory requirements.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the trial publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the trial will be given; and that any discrepancies and serious breaches of GCP from the trial as planned in this protocol will be explained.

**For and on behalf of the Trial Sponsor:**

Signature: Date: .

Name (please print): Ms Pam Baxter

.....

Position: Senior Research Governance Officer

.....

**Chief Investigator:**

Date: 05.06.2023

Signature: 

Name (please print):

Paul Farrand.....

KEY TRIAL CONTACTS AND GENERAL STUDY BACKGROUND

**Table 3 Key contacts**

| | |
|---|---|
| Chief Investigator | Professor Paul Farrand, Sir Henry Wellcome Building for Mood Disorders Research; Clinical Education, Development and Research (CEDAR), Psychology; College of Life and Environmental Sciences; University of Exeter, EX4 4QG. 01392 724793, p.a.farrand@exeter.ac.uk |
| Project Administrator | Nicole Madeley, Sir Henry Wellcome Building for Mood Disorders Research, School of Psychology, College of Life and Environmental Sciences, University of Exeter, EX4 4QG. |
| Trial manager | Dawn Phillips, Exeter Clinical Trials Unit, College of Medicine and Health, University of Exeter, College House, St Luke's Campus, Magdalen Road, Exeter, Devon, EX1 2LU d.phillips4@exeter.ac.uk |
| Sponsor | University of Exeter<br>Sponsor's Representative<br>Ms Pam Baxter<br>Senior Research Governance Officer<br>University of Exeter, Research Ethics and Governance Office, Lafrowda House<br>St Germans Road, Exeter, Devon EX4 6TL<br>Email: p.r.baxter2@exeter.ac.uk<br>Tel: 01392 723588<br>Mobile: 07485042117 |
| Funder(s) | UKRI Medical Research Council |
| Clinical Trials Unit | Lynne Quinn/Siobhan Creanor, Exeter Clinical Trials Unit, College of Medicine and Health, University of Exeter, College House, St Luke's Campus, Magdalen Road, Exeter, Devon, EX1 2LU, 01392 726 037<br>https://ctu.exeter.ac.uk |
| Key Protocol Contributors | Ed Watkins |
| Statistician | Professor Gordon Taylor, College of Medicine and Health, University of Exeter, College House, St Luke's Campus, Magdalen Road, Exeter, Devon, EX1 2LU, 01392 726 037<br>Dr Fiona Warren, Institute of Health Research, University of Exeter, Devon, 01392722749, f.c.warren@exeter.ac.uk |
| Site Team | University of Exeter (Trial Manager, project administrator and chief investigator (contacts above) |
| Other sites: recruitment only | Nil |

**Table 4 Collaborators**

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|---|
| Ed Watkins |
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| |

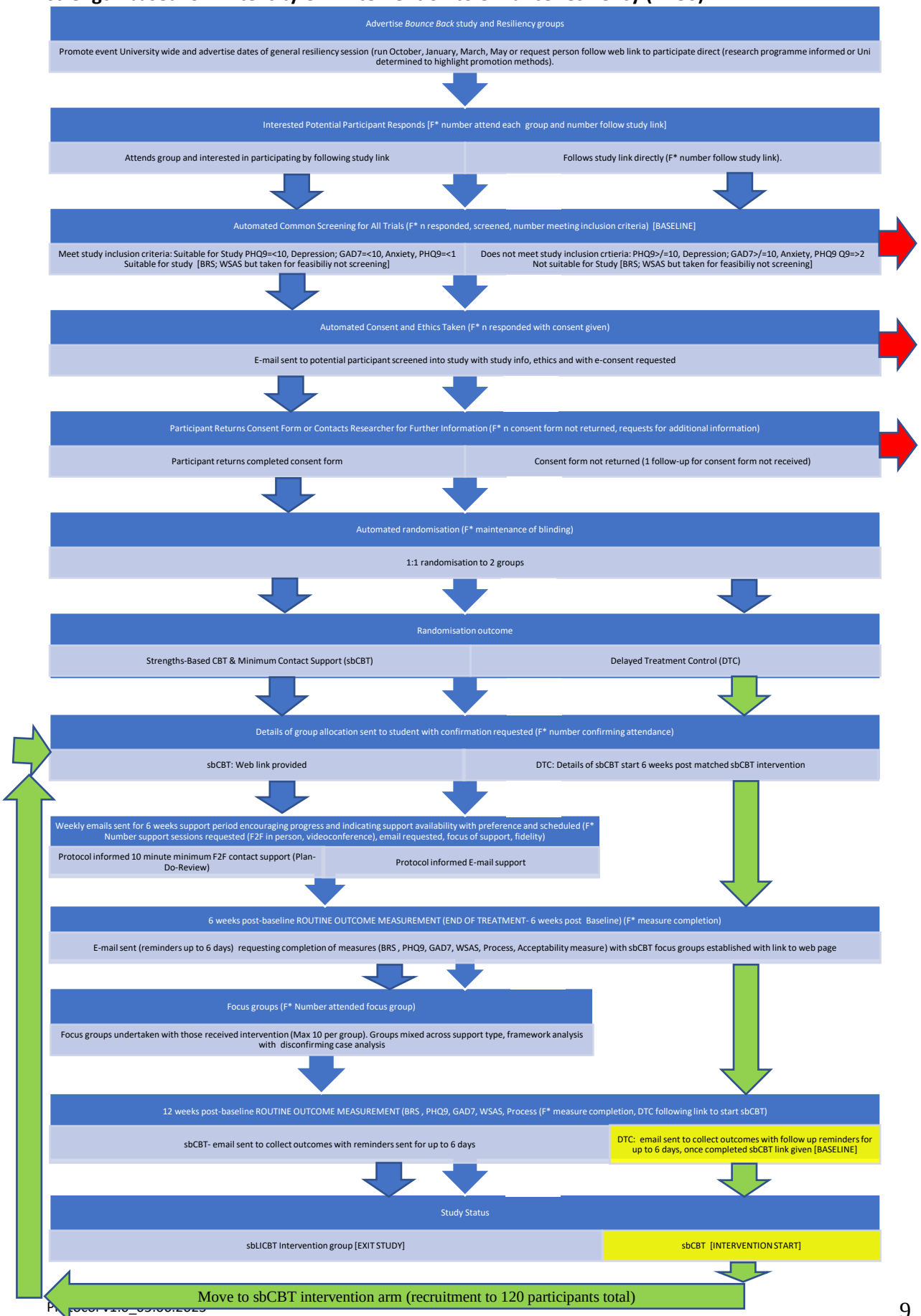
**Table 5 LIST of CONTENTS**

**Table 6 LIST OF ABBREVIATIONS**

| | |
|---|---|
| AE | Adverse Event |
| AES | Advanced Encryption Standard |
| AR | Adverse Reaction |
| CI | Chief Investigator |
| CBT | Cognitive Behavioural Therapy |
| CDISC-CDASH | Clinical Data Interchange Standards Consortium – Clinical Data Acquisition Standards Harmonisation |
| CRF | Case Report Form |
| CRO | Contract Research Organisation |
| CTU | Clinical Trials Unit |
| DMC | Data Monitoring Committee |
| DMEC | Data Management and Ethics Committee |
| eCRF | Electronic Case Report Form |
| EDC | Electronic Data Capture Form |
| ERUS | Enhancing Resiliency in University Students (Study acronym) |
| GCP | Good Clinical Practice |
| GDPR | General Data Protection Regulation |
| ISRCTN | International Standard Randomised Controlled Trials Number |
| LICBT | Low-Intensity Cognitive Behaviour Therapy |
| PI | Principal Investigator |
| PWP | Psychological Wellbeing Practitioner |
| RCT | Randomised Controlled Trial |
| REC | Research Ethics Committee |
| SAE | Serious Adverse Event |
| SAP | Statistical Analysis Plan |
| SAR | Serious Adverse Reaction |
| sbLICBT | Strength-Based Low-Intensity Cognitive Behavioural Therapy |
| SOP | Standard Operating Procedure |
| SUSAR | Suspected Unexpected Serious Adverse Reaction |
| TIDieR | Template for Intervention Description and Replication Checklist |
| UNEXE | University of Exeter |

FEASIBILITY TRIAL FLOW CHART

**Figure 1 Illustration of feasibility with embedded pilot randomised controlled trial for written strength-based low-intensity CBT intervention to enhance resiliency (ERUS)**



# 1 BACKGROUND

From a student perspective, the role of university is to educate and inspire learning, facilitate finding employment in a desired area and develop their careers (Chan, 2016). University life also presents students with the opportunity to establish greater independence, acquire problem solving and coping skills alongside developing a range of transferable skills (Dennis, Smith & Wadsworth, 2014). In addition to presenting opportunities however, students are also faced with challenges associated with transition to university life (Hettich, 2010) and daily living, such as pressures arising from increasing financial demands. Increasingly demands are also faced as universities adopt pedagogic approaches (Levy & Petrulis, 2012), to ensure graduates develop proficiencies that meet demands placed on them by employers (Arvanitakia & Hornsby, 2016). Placing significant demands on students to organise, manage and take greater responsibility for their own learning, alongside dealing with wider pressures is resulting in an increasing number of students scoring lower on specific dimensions of a resiliency index (Arvanitakia & Hornsby, 2016). Increased exposure to such demands is therefore placing university students at an increased likelihood of experiencing mental health (MH) difficulties (Auerbach et al., 2018), that can translate into long term-disadvantage (Duffy et al., 2020). Efforts to promote positive emotional wellbeing in students are therefore required placing increased pressure on universities to improve the resiliency of students by taking a proactive approach to enhance mental wellbeing in the student population (McIntosh & Shaw, 2017).

Efforts made by universities to address the emotional wellbeing of students are largely targeted at the treatment of mental health difficulties by wellbeing services once symptoms reach a level having a significant impact on their study and wider lives (Barkham et al., 2019). However, to improve access to wellbeing services whilst avoiding commonly experienced long waiting times (Priestly et al., 2022) would require significant investment. Whilst the need for increased investment is commonly raised by students themselves (Baik, Larcombe & Brooker, 2019), substantially increased long-term funding to expand wellbeing services to treat the increased prevalence of mental health difficulties in university students is unrealistic (Auerbach et al., 2018). Simply increasing funding alone to improve access to mental health services has already been recognised as unrealistic to meet increased demand within the statutory sector (Farrand, 2020).

Additionally, solely focussing on increased funding to expand University wellbeing services would likely do little to address many barriers to mental health help-seeking in university students. These include the perception that treatment is not needed, lack of time (Ewa et al., 2013), poor mental health literacy and preference for self-reliance (Gulliver, Griffiths & Christensen, 2010). However, perceived stigma regarding mental health represents the most common reason not to seek treatment (Eisenberg et al., 2009). Given an increased likelihood of being recognised within the student community, this is a particular concern for students given a fear of being the subject of gossip amongst other students (Leijdesdorff et al., 2021). Furthermore, merely focussing on increased funding without addressing help-seeking barriers would be unlikely to improve access for students that are male, Asian, international, more religious, or from a poor family that are also at an increased risk of developing mental health difficulties (Eisenberg et al., 2009).

An alternative approach to addressing increased prevalence of mental health difficulties whilst overcoming help-seeking barriers could be to focus on indirect prevention (Cuijpers, 2021). Implementing indirect intervention interventions to target mechanisms associated with mental health difficulties before they begin to have a significant impact and develop into problems that require treatment offers a potential solution. For example, in the treatment of insomnia with sub-threshold depression, an indirect prevention approach targets the insomnia to prevent the development of depression. Evidence indicates that using an approached informed by Cognitive Behavioural Therapy to directly target insomnia does not merely reduce insomnia but prevents depression (van der Zweerde et al., 2019). Focussing on mechanisms that can lead to mental health difficulties in University

students has potential to reduce the demand for treatment. This would help to address demands for increased investment in Wellbeing services (Baik, Larcombe & Brooker, 2019, and reduce reliance on interventions directed at improving help-seeking (Ebert et al., 2019).

Given increasing challenges faced by university students, focussing an indirect prevention approach on enhancing resiliency may be especially appropriate. When applied to a university context, resiliency accounts for academic success in the face of adversity that arise from challenges university life can present (Holdsworth, Turner & Scott-Young, 2018). An approach based on Cognitive Behavioural Therapy has recently been developed to target resiliency (CBT; Padesky & Mooney, 2012). The intervention is a high-intensity strength-based Cognitive Behavioural Therapy (sbCBT) adopting a four-step model to address resiliency. The therapist supported intervention enables the patient to identify their strengths to construct a Personal Model of Resilience PMR and apply this to an area found challenging. Engaging with the intervention the therapist enables the patient to recognise the hidden strengths they have and bring these into awareness to enhance resiliency when applying these to challenges subsequently faced.

Recent developments have been undertaken to facilitate adoption of the sbCBT intervention to enhance resiliency in university students. To enhance reach and student engagement the intervention has been co-created and adapted into written low-intensity CBT (liCBT) self-help (Farrand, 2020). Adopting a liCBT intervention provides greater flexibility in delivery with emphasis placed on the user working through the intervention in their own time with support capable of being provided through a variety of modalities. Enabling students to engage with the intervention in their own time with a range of support options available when needed serve as facilitators to implementation into a university context. Providing an initial group-based session for students engaging with the intervention to capitalise on benefits associated with normalising challenges faced by university life serve as additional facilitators (Batchelor et al., 2020). Additionally, providing an initial group session would potentially help establish a sense of community and facilitate a culture where problems are shared rather than tolerated alone (Pernice et al., 2020).

This feasibility study with embedded pilot RCT seeks to examine methodological factors and potential effectiveness of an indirect prevention approach based on written LICBT intervention with ‘on demand’ face-to-face or email support to enhance resiliency in university students (Farrand Fang & Holmes, 2018). The approach is based on an adaptation of a high intensity strength-based Cognitive Behavioural Therapy (sbCBT; Padesky & Mooney, 2012) that adopts a four-step model to address resiliency. Supporting students recognise potentially hidden strengths and bring these into awareness is central to the intervention. Whilst the sbLICBT intervention was developed in collaboration with university students, additional focus groups will be undertaken to examine intervention acceptability and may serve to inform additional adaptations.

## 2 RESEARCH QUESTION

What methodological factors are faced when running pilot RCT to examine the potential effectiveness of a written strength-based low-intensity CBT (sbLICBT) intervention with choice of ‘on demand’, face-to-face or email support to enhance resiliency in university students and is it acceptable?

## 3 STUDY OBJECTIVE

To determine methodological factors faced when running a pilot RCT to examine the potential effectiveness of a written sbLICBT intervention with ‘on demand’ face-to-face or email support to enhance resiliency in university students and examine intervention acceptability.

## 4 KEY WORDS

Resiliency, low-intensity, CBT, indirect prevention, support, feasibility, pilot, RCT, University

# 5 STUDY SUMMARY

**Table 7 Study summary**

| | | |
|---|---|---|
| Title | Developing and Evaluating a Stepped Change Whole-University approach for Student Wellbeing and Mental Health: Feasibility Study with Embedded Pilot RCT of a Written Strength-Based Low-Intensity CBT Intervention to Enhance Resiliency | |
| Internal ref. no. (or short title) | ERUS (**E**nhancing **R**esiliency in **U**niversity **S**tudents)<br>Bounce Back | |
| Clinical Phase | II | |
| Trial Design | Phase II single centre feasibility RCT with embedded pilot. | |
| Trial Participants | UK university students | |
| Planned Sample Size | 120 | |
| Treatment duration | 6 weeks | |
| Follow up duration | Twelve weeks post-randomisation | |
| Planned Trial Period | 28 weeks (starting first group session to final follow-up) | |
| | **RCTs & measures** | **Outcome domains** |
| **Primary outcome** | Feasibility outcomes | Feasibility |
| **Secondary outcomes** | Brief Resiliency Scale – BRS<br>Depression – PHQ9<br>Anxiety – GAD-7<br>Work and Social Adjustment Scale (WSAS) – Functioning | Resiliency<br>Indices of well-being and poor mental health<br>Non-specific indices of poor mental health |
| Mediators | N/A | |
| Intervention | One intervention group<br>Written strength-based CBT intervention with choice of support on demand (email, face to face [in person v. videoconference]) for up to 6 weeks<br>Control is delayed treatment control | |
| Route of Administration | Written CBT workbook with 'on demand' support | |

## 6 TRIAL MANAGEMENT/RESPONSIBILITIES

A dedicated trial manager will assist with the day-to-day management of the project and be responsible for effective communication and monitoring progress. The trial will be managed by a core research team who will meet weekly with bi-monthly meetings via teleconference or video-conference with the Principal Investigator to review progress and set targets. The trial manager will be mentored by an EXCTU senior manager. The trial will be registered with https://www.isrctn.com/ and assigned an ISRCTN number. Researchers will be trained in Good Clinical Practice. We will comply with the UK Department of Health Research Governance Framework for Health and Social Care. The trial will be conducted to protect the human rights and dignity of participants as reflected in the 1996 version of Helsinki declaration. Trial documents will be retained for a period of 10 years after the completion of the study as detailed in the Patient Information Sheet.

### 6.1 Patient registration/randomisation procedure

At the point of randomisation participants will be automatically registered on to the trial using the electronic data capture (EDC) system. Randomisation is after the online consent, the screening process and after the online baseline assessment. There is a two-part consent process which in the first part asks for permission to screen and take part in the assessment. The second part of consent with agreement sought to take part in the study is taken prior to baseline assessment. Participants can stop the assessment at any stage and be emailed a link to return the screening website. this allows them to have time to consider the participant information which they have read on screen and which is emailed to them. The email link will be live for 14 days. After this time the participant will need to contact the site to ask for the link to be reset.

### 6.2 Data management

There is a separate data management plan which accompanies this trial protocol which gives greater detail.

*No data will be collected or used without the explicit informed consent of the participants.*

During the project, the team will stipulate any conclusive needs within the project regarding participants' data. This may refer to the temporariness of data storage, security of data transfer, relevant consent applications and relevant advertisement of the use of the data. To safeguard the confidentiality of the participants' personal information, such data will be stored in a record that will be kept locked in the institution. Only the researchers will be aware of this personal information. For research purposes each participant will be given a numerical code (to be used in place of a name). The technology should cater for the fact that each participant will be given a unique identification code, rather than a name, and all data will be securely stored and preserved, both electronically and on paper.

Only authorised research personnel will have access to the password protected electronic database. No unauthorised access will be possible. A separate list linking codes with names will be kept in a secure place. The data will be introduced and analysed by computers. As for Internet use and monitoring by means of mobile apps, data protection systems will be designed (using secure passwords, encryption, etc.). The researchers will have access to the database using a password. Also, to protect all information, we will follow the AES (Advanced Encryption Standard) strategies for personal password use and data encryption. The study researchers will promise to not reveal data from which personal and health information about the participants could be deduced. The same principles will be taken into consideration in the dissemination of data in the publication of scientific papers and the presentation of research reports at scientific conferences.

**Database infrastructure:** The project will use a distributed electronic database (managed by UNEXE, Partner 1) during the project that will store all the downloaded cohort data and clinical trial data. Within the clinical trials, UNEXE will be in charge of the set-up and management of the database. The equivalent of anonymised electronic Case Report Form (eCRF) data will be set-up and entered in a data management system, which is fully validated. The eCRF and associated database will be automatically populated from the responses entered by participants via websites and app platform: data will be encrypted and anonymised before downloading from the website or app and then stored securely and converted into an electronic database suitable for analysis. A data manager will be appointed to build and manage the database infrastructure. Data will be routinely backed-up during and after the project to ensure the availability of all the information.

**Data Management Plan:** The Data Management Plan will describe how the data will be exploited, checked, shared, curated and preserved. Thus, the procedure for granting access will be detailed and the mechanisms to access the data after the project will be described. The ownership of data generated during the project will be described in the Consortium Agreement.

**Data format and types:** Standard data formats will be used during the project and will be compliant with Clinical Data Interchange Standards Consortium – Clinical Data Acquisition Standards Harmonisation (CDISC-CDASH) standard. Data types will include Volunteer data: Demographics, information provided by participants on questionnaires and on EC assessment instruments.

**Data exploitation:** All information will have a digital format that will be handled in accordance with European and national data protection regulations. A mechanism to request access, mine, exploit, reproduce or disseminate data generated in the framework of this project will be put in place. After successful evaluation by the consortium, access to the project data may be granted to other parties, following rules that will be defined in a specific agreement between the partners and third parties.

## 6.3 Data protection/confidentiality

### 6.3.1. Data protection

The conduct of the project will comply with GDPR. Adequate measures to ensure data protection and confidentiality will be duly taken into account by the project team. Local and national rules on data protection will be followed and no personal information of participants will be transferred unless such transfer is essential for the conduct of the trial.
A privacy impact assessment (data protection impact assessment) will be carried out if requested by the funder, ethics committee or sponsor. If one is carried out it will be conducted according to the guidelines of the UK Information Commissioners Office: Conducting privacy impact assessments code of practice, Information Commissioner's Office (ICO), 2014.
https://ico.org.uk/media/fororganisations/documents/1595/pia-code-of-practice.pdf.

Data will be stored in separate databases that are linked by the unique identifier ID to pseudonymize all information collected. The first database contains information related to informed consent and information enabling researchers to directly contact participants. On the screening website, participants are not asked to provide their name or any contact details until they have been provided with the participant information sheet and privacy policy. At the point of asking participants to consent to take part in the assessment, they are asked for their name, email address and phone number. The second database contains all the baseline and follow up data collected from the EDC system. The codes linking contact information with the database containing outcomes will be destroyed as early as is legally required (no earlier than all data being archived) – data (including participant details and consent) may need to be retained and not deleted for a longer period due to future research indicators that may require researchers to contact the individual or actions taken by participant against the

research. This approach has proven successful in prior digital interventions for well-being and been approved by multiple institutional and National Health Service research ethics in the UK; adaptations will be made as necessary for specific local ethical requirements.

The site research team will have access to the database that connects the ID number to a person and their full contact details. This is so that they can contact the participant if they report technical difficulties, if any suicide risk is indicated, and to send reminders regarding assessments. Email and text for reminders will never contain personal or other information about the collected data, but remind participants, in a general manner, about open tasks. Exeter Nurture-U researchers, clinicians and the chief investigator only will be set up with a username and password to access the CTU database that stores the personal data. The researchers are not given the allocation details so as to maintain blind.

### 6.3.2 Digital Information

Files containing digital information must be encrypted with password-protection where appropriate and stored on a secure network (not a local 'C') drive. Where local copies are required for processing or transfer preparation, it should be ensured that the target workstation is compliant with all host organisation security policies and that they are followed in use. This is particularly important for laptops/netbooks/portable workstations, especially about encryption and should be confirmed by the host organisation before transferring data. The relevant university guidelines and policies will be followed (e.g., for the University of Exeter, the University Information Security Policy, and the University Computing Regulations – a copy of the specific University guidelines for portable devices is available here: http://alf.exeter.ac.uk/share/s/GwluvMWoQn-_FPAwNFxS7g. Participants identifiable data must not be stored on home computers, personal laptops, unencrypted memory sticks, CDs, handheld devices, digital cameras or other imaging equipment even if they are password protected. An encrypted memory stick may be used if required.

All data generated will be stored by University of Exeter in encrypted and password-locked files behind a secured firewall operating within a university environment with state-of-the-art safety protection measures, and transmission of information via electronic means will be performed using encrypted data files. The exact process for data storage and encryption for the data processors will be directed by the data controller and outlined in the data management plan.

### 6.3.3. Participant data

Participant confidentiality and welfare will always be maintained as the highest priority. Anyone with access to data, including the investigators, is subject to professional secrecy during and after the trial. We do not anticipate any sharing of data from this clinical trial with sites outside of the EU during the course of the project.

Anonymised data (health information, socio-demographic information, platform usage information) will not be deleted until the completion of the scientific analysis of the data plus the mandatory period for retaining clinical data (at least ten years in the UK).

### 6.3.4 Responsibility

The University of Exeter as sponsor of the trial is the data controller. The controller has the responsibility to ensure that the security and access arrangements for the database comply with the Data Protection Act (1998), and that all data processing and locally held personal data are registered with the host institution according to their employer's processes. Because this trial involves the

processing of personal information the Information Commissioner's Office (ICO), will be notified accordingly.

Legal data transfer agreements will be written and signed between the data controller and data processors prior to any participant being recruited, where appropriate. These agreements will be confirmation that the data processors will adhere to GDPR regulations, which protect and safely store participant personal and outcome data.
A common data protection and privacy policy authorised by the sponsor and the University of Exeter data protection team will be available on the study website. The screening website will also email this policy to consenting participants with the information sheet and consent form or provide it as a download.

### 6.3.5 Data Monitoring

Data will be accessed by the trial manager / data manager on the EXCTU data base on a regular basis (typically at least weekly) to check recruitment numbers and data quality and to monitor that all processes are working correctly. Detailed checks will occur early in the project to confirm that all systems are working properly. To download data the trial manager has to login via user name and password.

### 6.3.6 Breach of confidentiality

Occasionally records containing personal data that should not have been disclosed, e.g. an e-mail with a data file containing identifiable details may be received by a member of CTU staff or another staff member from an internal or external source. In such situations, the member of staff should contact the person who sent the data and make them aware of the breach of confidentiality. The records received should be either promptly deleted or any identifying details thoroughly erased. All suspected breaches should be investigated, documented in the study file and reported to the Sponsor as appropriate, following an established data breach the UNEXE procedure will be followed.

## 6.4 Trial documentation and archiving

The materials for the trial will be submitted with this study protocol.

Source documents, and trial-related electronic and other data will be stored safely and in accordance with the requirements of the UK GDPR and Data Protection Act (1998), no longer than legally required (for a minimum of ten years) or as stipulated by the Sponsor's requirements, and the applicable regulations and as per the Clinical Trial Units existing Business Continuity, Disaster Recovery & Archiving Standard Operating Procedures.

Data Access: Post-analysis, the final anonymised dataset will preferentially be stored in Open Research Exeter (ORE), the University of Exeter's open access repository.

Interoperability: Source data will be stored in Microsoft SQL server, formatted to maximise fidelity. This can be transposed and converted during the analysis stage into any format required. For the Open Research Exeter repository XML or CSV with a separate data dictionary is recommended.

Archiving: Items submitted to ORE will be retained indefinitely. ORE content is securely held on University of Exeter servers and regularly backed up according to current best practice. The ORE team will also try to ensure continued readability and accessibility of content, including the migration to new file formats where necessary.

Data archiving is described in further detail within the Data Management Plan.

### 6.5 Authorisation of participating site

The study is single site located at the University of Exeter. The site will be authorised after ethical approval has been given by the School of Psychology ethics committee and a data transfer agreement is in place with the UNEXE data controller. The trial manager will ensure the site is adequately staffed, staff researchers have access to a clinical adviser, and that site staff are familiar with the standard operating procedures, risk assessment procedures and that Good Clinical Practice (GCP) and General Data Protection Regulation (GDPR) standards will be followed.

### 6.6 Required documentation

Before recruitment can begin at sites, staff CV's and evidence of good clinical practice and GDPR training will be collected. Each site will be provided with copies of the standard operating procedures for the trial. Each site will create a resource of online links and local and national services for those indicating that they have current depression, suicide risk, mania and psychosis. These links will be checked before the trial starts and at monthly intervals during recruitment to ensure that these details are kept up to date.

## 7. PARTICIPANT INCLUSION/EXCLUSION CRITERIA

**Table 8 Inclusion/Exclusion criteria**

| Inclusion | Exclusion |
|---|---|
| Aged 16 or over. | AGED 16< |
| PHQ9=<9; GAD7=<9 | PHQ9>9; GAD7>9 |
| Suicide risk: PHQ9; Q9=<1 and R2=No and R3= No | Suicide risk: PHQ9; Q9>1 and R2=Yes and/or R3 =Yes |
| Resident in UK | |
| Student at the University of Exeter | Past history of psychosis, mania, substance/alcohol dependence |

## 8. TRIAL PROCEDURES

### 8.1 Participant identification

We will recruit from the general university population at University of Exeter. Posters, emails, websites, presentations, and social media will all advertise the study for students who wish to tackle anxiety and depression. Recruitment of the cohort will follow successful models (e.g., http://www.mappiness.org.uk/, 66,000 participating). Using proven methods, researchers will recruit participants through:

- multiple traditional and social media (posting and advertising on Facebook, YouTube, Instagram, SnapChat, Google, MySpace, Twitter, TikTok, study website, through media influencers/vloggers, etc adjusted by cost/frequency as needed); social media analytics will be used to enhance recruitment;
- app store, Googleplay store;
- email circulars and local promotion (posters, emails, newsletters, signposting by staff) to university departments;
- snowballing approaches;

## 8.2 Screening

Participants will be screened by an EDC system set-up and managed by Exeter CTU for university students - those under 16 will automatically be screened out pre-assessment. Website users who report having current risk will be taken to the feedback screen where they will be advised that we are sorry to hear that they are feeling that way, to please contact their GP and to give them sources of online help and support.

## 8.3 Consent

We anticipate that university students will be autonomous independent young adults who are legally recognised as being at or above the age of majority and able to provide their own informed consent to their participation in research (aged 16 or over for the UK).

Young people will be initially routed to or seek out the study website and will be provided with the participant information sheet, consent form A and data protection policy to review on the trial electronic platform, prior to completing screening measures. There will be a check box at the bottom of the information sheet which participants will need to check before they can sign the consent form. Participants will then be asked to read, date, and electronically sign consent form A and provide their contact details. Consent form A asks for consent to undertake the assessment and confirmation that the participation understands the nature of the study.

When consent is given, they will be assigned a screening ID number and automatically be emailed a copy of the consent form, information sheet and data protection /privacy policy or given the option to download these documents. The recruit will then be asked to complete brief background screening measures to determine eligibility on the online screening website. Non-excluded recruits can stop and save their assessment at any time and be emailed a link to return to the assessment. The participant will have 2 weeks in which to be able to return to their part completed assessment. After this time, they would need to start the assessment again if they wanted to take part.

If a participant completes the screening assessment and is eligible for the trial, then they will be presented with consent form B1 which asks them to consent to taking part in the trial. Recruits are advised that they can take time to consider taking part and can save their assessment whilst they do so.

On completion of consent form B1 participants are then asked to complete the full baseline assessment measures. Once this has been completed, the recruit is randomised and will be given a unique study participant trial number, and they are informed that they have completed the baseline assessment and that they will be contacted to be informed of the outcome of the randomisation.

All participants will be given the option to seek further information from the research team, with contact details to the relevant research team provided (email, and/or telephone number as available). This information will be provided on all versions of the information sheet and on the help menu of the study website.

## 8.4 The randomisation scheme

The feasibility with embedded RCT will follow MRC Complex Interventions Guidelines and relevant CONSORT reporting requirements with a pre-registered trial protocol. Randomisation will be in equal allocation (e.g. 1:1) using independent computerised randomisation. Random selection to the 2 arms (sbLICBT vs delayed treatment control) will be conducted automatically by means of a secure service created and managed by the Exeter Clinical Trials Unit (CTU) in conjunction with the trial statistician. This will be independent of the trial researchers.

## 8.5 Protection from bias

We will adopt prior registration and publication of the trial protocol. Independent web-based computerised randomisation will be conducted to ensure generation of an unpredictable allocation sequence and concealment of participant allocation and of allocation sequence and prevent selection bias and confounding. We will use standardised self-report outcome measures with data collected

automatically through the website. The use of self-administered measures will eliminate observer bias. A detailed statistical analyses plan will be prepared before any analysis is conducted. The trial statistician will remain blinded to group allocation until the main data analyses have been undertaken and interpretation of the trial results have been agreed by the relevant committees. Attrition bias will be minimised by having robust trial procedures to prevent data loss such as email, text, and phone reminders to encourage follow ups.

## 8.6 Method of implementing the randomisation/allocation sequence

Participants will be randomised by a web service which interfaces with the EXCTU EDC system and database. This will be an automated process. The EXCTU database will send an unblinded team member (administrator/therapist) indicating when an individual [by study ID] has been randomized to the active intervention. This team member will then access the relevant details in the EXCTU database and manually set up the participant in the internet platform using administrator rights via the internet platform dashboard. A system automated email will be sent to the participant indicating the condition to which they are randomised, informing them what to expect, date of sbCBT group to next intervention arm and asking the participant to confirm receipt by return of email to unblinded team member. The team member will send up to 6 reminder emails to any participant that has failed to confirm receipt.

Failure to receive confirmatory email: the relevant unblinded team member will also be able to monitor if the participant has accessed the intervention and check if there are any difficulties and encourage to sign-up.

Detailed procedure for randomisation:

1. Participants are block randomised (30 participants per arm) into the 2 arms (DTC control versus sbLICBT) on an intention-to-treat basis.
2. Block randomisation will continue until 120 participants (6 iterations of 60 participants) are randomised.
3. The system must record the allocation and the date randomised.
4. The trial manager and at least one other researcher remain blind to the allocation; the participant will be aware of which intervention received. Thepractitioner/ administrator will be unblinded in order to set-up participant on internet platform.
5. On successful randomisation, a finish page is displayed with a message telling the participant to look for an email message from the trial team.

## 8.7 Blinding

The follow up data will be routinely collected online using the website/EDC system (and the reminders for this will be sent out automatically by email from the EDC system). This will prevent the follow up results being affected by the site researcher. Trial researchers who will be blind to treatment allocation include the Chief Investigator and Trial Manager. The Trial Manager will be in direct contact with participants to answer technical queries. The trial therapists will be unblinded and will be in direct contact with participants to follow up risk. It is possible that a site researcher could become unblinded during those (infrequent) conversations if the participant mentions details of the intervention and this will be recorded as part of the feasibility focus.

Should a blinded site researcher become unblinded then this will be logged as an unblinding and any telephone-based chasing of follow up data for that participant in future will be conducted by another blinded researcher at the site (if available). Therefore, only blinded site researchers will attempt to collect the primary outcome measures by telephone if the participant is unwilling to use the screening website for this purpose. Unblinded site researchers will not discuss information relating to condition with blinded site researchers. During any contact with participants the blinded site researcher will remind them not to divulge to which condition they were allocated. In the event that there are no

unblinded researcher at a site and telephone collection of follow up primary outcome is possible, this data will be collected, but will be logged and clearly marked as 'collected unblinded'. This will allow the statisticians to control for this in their analysis. The statisticians will be blinded to intervention until the analysis is done and they are interpreting the results.

### 8.8 Emergency Unblinding

It is extremely unlikely that a site researcher other than the administrator/practitioner responsible for setting participants up on the intervention would need to be unblinded, even in cases of risk. The trial code would only need to be broken for valid medical or safety reasons, for example in the case of a serious adverse event, where it is necessary for the investigator to know whether there is a relationship between condition and adverse events. In these circumstances, the research team will remain blinded. Where a person raises clinical relevant concerns or reports risk, and where knowing the trial condition is relevant, one of the project team dealing with this participant can potentially be unblinded to the participant's condition to support their care and further support them – in many cases, it may not be necessary to know the condition. The action taken according to the risk protocol would be the same, regardless of condition. The PI will be able to request the condition from the CTU if there are any adverse events. In the case of a serious adverse event, it will be necessary for principal investigator / site-relevant practitioner to be unblinded for safety reasons.

### 8.9 Baseline data

Baseline data will be collected after the screening section of the screening website.

### 8.10 Trial assessments

Assessment will take place at baseline (start of treatment) and then at 6 weeks post baseline (equating to end of treatment) and 12-weeks post baseline. The 3-month follow up will be the primary endpoint. All assessments will be through EXCTU managed EDC system. Only if participants have not responded to email and text prompts to complete their follow ups at 6 and 12 weeks will they be contacted by phone and asked to provide the primary outcome measures only on the telephone. The results of the assessments are only to collect research data for the trial and will not be provided to medical practitioners. The only exception to that would be if a participant indicates suicide risk and asks us to provide their assessment results to their medical practitioner. They would need to give written consent for this and provide us with the contact details to do so. See risk protocol in Appendix.

At the end of treatment, participants that have received the sbLICBT resiliency intervention will receive an email asking them to participate in an acceptability focus group and Section 12 of the protocol provides further information on this.

### 8.11 Long term follow-up assessments

Participants will be followed up at 6 and 12 weeks post baseline.

**Table 9 Procedures schedule**

| **Procedures** | **Screening** | **Baseline** | **6 weeks post-baseline follow-up** | **12 weeks follow-up** |
|---|---|---|---|---|
| Informed consent | Yes | Yes | No | Yes |
| Demographics | Yes | No | No | No |
| Mental Health History | Yes | No | No | No |

| | | | | |
|---|---|---|---|---|
| Eligibility assessment | Yes | No | No | No |
| Randomisation | No | Yes | No | No |
| Access to intervention | No | Yes | Yes | Yes |
| Assessment of wellbeing and depression | Yes | Yes | Yes | Yes |
| Assessment of current functioning | No | Yes | Yes | Yes |
| Feasibility outcomes | No | No | No | Yes |
| Adverse event assessments | No | No | Yes | Yes |

### *8.11.1* Payment

Participants will be paid in electronic vouchers for taking part in the 6 weekly measures and after completion of the 12 weeks follow up. We will pay £10 for completing the 6 weekly post-baseline assessments and the 12 weeks follow up.

Researchers will be able to run reports on the Exeter CTU database to identify which participants have completed follow ups at the key payment points (after 12 weeks). Site researchers will arrange for the payment of participants using electronic shopping vouchers, which can be emailed or sent by text or via direct bank transfers. No travel expenses are anticipated for participants as all assessment and intervention contents are provided remotely via digital platforms (website, app).

## 8.12 Withdrawal criteria

Participants can choose whether they want to stop using the sbLICBT intervention, or if they want to withdraw from the trial completely (including all assessments) at any time. Participants will also be withdrawn from the trial if the site clinical advisor, or the participant's medical practitioner advises that this is best for their wellbeing. A log will be kept of the participant number, reason for and date of all withdrawals from the trial. Participants who met the inclusion and exclusion criteria at baseline will not be replaced. Participants who did not meet the criteria at baseline can be replaced and their data removed from the data set. Participants who withdraw from the trial will not be followed up. Once a participant withdraws, all email and text notifications that are set on auto will be removed.

## 8.13 End of trial

The final follow ups were due in March 2023 (but this has been revised to June 2023) and the project was expected to end June 2023 but this has been revised to February 2024. Any early termination of the trial will be reported to the ethics committee within 15 days.

## 8.14 Assessment of treatment engagement

Brief questions at 6 week post baseline will assess engagement with the sbLICBT intervention with regards to average frequency and time per week.

# 9 INTERVENTIONS

## 9.1 Written Strength-Based Low-Intensity CBT (SBLICBT) Resiliency Intervention with Support on Demand

The intervention is reported according to the Template for Intervention Description and Replication (TIDieR) Checklist (Hoffman et al., 2014).

**Table 8 TIDieR Checklist**

| Item | Description |
|---|---|
| Brief Name | Bounce Back: Finding Your Inner Strength |
| Why | As a consequence of being exposed to increasing demands presented by University life, students now have an increased likelihood of experiencing mental health difficulties resulting in long-term disadvantage. Enhancing resiliency to enable students to cope when facing such demands has potential to prevent the development of mental health difficulties. A protocol for a strength-based CBT intervention (Padesky & Mooney, 2012) has informed the development of a written low-intensity CBT intervention. To enhance resiliency, the participant engages with the written intervention to work through four-steps –(1)Record a successful regular activity, (2)Build a personal model of resiliency, (3)Apply personal model of resiliency to an area found challenging, (4)Practice resilience. |
| What | Written strength-based low-intensity CBT intervention with an initial 60-minute didactic group session to provide an overview of the resiliency intervention and introduce availability of 'on demand' support. On-demand support will be available face to face, virtual, phone or by email for up to 6 weeks. |
| Who Provided | A Psychological Wellbeing Practitioner (PWP) trained to support the intervention with supervision provided. |
| How | Following a 60-minute didactic group session where the intervention introduced, participants will be encouraged to engage with the written CBT self-help intervention over the following 6 weeks. 'On demand' minimum contact 'Plan-Do-Review' support will be available on request, over face to face or by email. |
| Where | University of Exeter. |
| When and How Much | First delivery from October 2022 (revised to June 2023). Following the initial group session, participants will be encouraged to engage with the intervention on their own over the next 6 weeks. It will be emphasised that engaging for a manageable amount of time on a regular basis is better than trying to use the intervention for a long period of time periodically. However, the exact amount of time the participant engages with the intervention will be determined by them. To recruit 120 participants will require 3 iterations (30 sbCBT and 30DTC) per iteration, with the final DTC group receiving the intervention outside of the study. |
| Tailoring | The intervention has been co-produced with undergraduate students for a population of university students. |
| Modifications | The intervention used within the study is a modification of a previous intervention developed for university students. Modifications include removing 'resiliency' from the title and changing to 'Bounce Back', alongside reducing the frequency of the term 'resiliency' in the text itself. |
| How Well | Fidelity to the email support protocol will be measured by comparing written support emails to a fidelity checklist informed by an e-mail support protocol (Hadjistavropoulos et al., 2018). |

## 9.2 Delayed Treatment Control (DTC)

Participants randomised into the DTC will receive the intervention when those initially randomised into the intervention arm have completed the 6-week intervention.

# 10 OUTCOME MEASURES/ENDPOINTS

## 10.1 Feasibility outcomes (Appendix 1)

**Table 9 Feasibility Outcomes**

| | | | |
|---|---|---|---|
| Number of people accessed study web site | | | |
| Number of people complete screening questions | | | |
| Number of people screened out | | If Yes - Reason | Report by demographics |
| Number of people consented | | | Report by demographics |
| Number of people randomised | | | Report by demographics |
| Blinding randomisation maintained | | Yes | No |
| Study arms | | | |
| sbLICBT | Number attended group session | Report by demographics | |
| | Number completed baseline outcome measure | Data completion of each item for each outcome measure | |
| | Difference in WSAS score screening v attended group session | Overall and score per item | |
| | Number completed end of treatment outcome measures (6 weeks post baseline) | Data completion of each item for each outcome measure | |
| | Number completed final outcome measures 12-week post baseline | Data completion of each item for each outcome measure | |
| | Number of participants requesting support | Report by demographics | |
| | Number of support episodes requested | | |
| | Number of each type of support episode requested | Face to Face | e-mail |
| DTC | Number completed baseline outcome measure | | |
| | Difference in WSAS score screening v baseline | Overall and score per item | |
| | Number completed outcome measures at 6 weeks post baseline | | |
| | Number completed final outcome measures 12-week post baseline | | |
| DTC move to sbLICBT | Number attended group session | Report by demographics | |
| | Number completed baseline outcome measure | Data completion of each item for each outcome measure | Number completed baseline outcome measure |
| | Number completed end of treatment outcome measures | Data completion of each item for each outcome measure | Number completed end of treatment outcome measures |
| | Number completed final outcome measures 12-week post baseline | Data completion of each item for each outcome measure | Number completed final outcome measures 12-week post baseline |
| | Number of participants requesting support | Report by demographics | |

| | | | |
|---|---|---|---|
| | Number of support episodes requested | | |
| | Number of each type of support episode requested | Face to Face | e-mail |

10.2 Outcome measures (Appendix 2)

**Table 10 Outcome measures**

| Measure | Description | Reliability and Validity |
|---|---|---|
| **SECONDARY OUTCOMES** | | |
| ***Brief Resiliency Scale*** **(BRS;** Smith et al., 2008) | 6-item participant rated questionnaire assessing ability to on a 5 point scale for each item with anchors –Strongly Agree and Strongly Disagree. Items 1, 3, and 5 are positively worded, and items 2, 4, and 6 are negatively worded. Scored by reverse coding items 2, 4, 6 and adding responses varying from 1-5 for all six items giving a range from 6-30 with total divided by number of questions answered. Interpretation: Low Resiliency=1-2.99; Medium Resiliency=3-4.30; High Resiliency=>4.31. | Commonly adopted measure of resiliency and has been used to rate resiliency in a large number of populations (e.g. University students; cancer) across many countries (e.g. UK, China, Brazil, Germany). Adequate test-retest reliability (.69) with good internal consistency Internal consistency was good, with Cronbach's α ranging from 0.80-0.91 across four populations varying in age. Within the two University student populations Cronbach's α = 8.84-0.87. |
| ***Patient Health Questionnaire-9 (PHQ-9;*** Kroenke et al., 2001) | 9-item participant rated questionnaire assessing frequency of symptoms of depression over the last 2 weeks. 4-point scale for each item, with anchors at 0=not at all, 1 = several days, 2= more than half the days, 3 =nearly every day. Unidimensional scale. Available in English, Spanish, German, and Dutch versions. | Leading measure of depression widely used in clinical trials, clinical practice, and as part of the NHS Quality and Outcomes Framework (QOF) for UK primary care, and Improving Access to Psychological Treatments (IAPT) Minimum Data Set (MDS). Cronbach's α =0.89 in primary care, test-retest reliability (ICC) 0.84 after 48 hours. Validation studies indicate positive correlations with measures of functional status (r=0.73), disability days (r=0.39), and symptom-related difficulty (r=0.55) At cut-off of ≥ 10, excellent specificity (0.88) and sensitivity (0.88) with diagnoses of major depression by structured interview, replicated in a UK population (sensitivity 0.80; specificity 0.92). |
| ***Generalized Anxiety Disorder-7 (GAD-7***; Spitzer et al., 2006) | 7-item participant rated questionnaire assesses frequency of symptoms of anxiety over the last 2 weeks. 4 point scale for each item, with anchors at 0=not at all, 1 = several days, 2= more than half the days, 3 =nearly every day. Unidimensional scale. Available in English, Spanish, German, and Dutch versions. | Leading measure of anxiety widely used in clinical trials, clinical practice, and as part of the UK NHS IAPT MDS. Cronbach's α =0.92, test-retest reliability ICC = 0.83. Convergent validity good, r =.72 with Beck Anxiety Inventory, r = 0.74 with Symptom Checklist-90 anxiety scale. |

| Measure | Description | Reliability and Validity |
|---|---|---|
| ***Work and Social Adjustment Scale (WSAS***; Mundt et al., 2002) | 5-item participant rated questionnaire assesses impaired functioning, rated from 0 not at all impaired to 8 severely impaired, with respect to work/education, home management, social leisure, private leisure, and close relationships. Unidimensional scale. | Leading measure of functioning, widely used in clinical practice, and as part of the UK NHS IAPT MDS. Cronbach's α range from 0.70 to 0.92, test-retest reliability ICC = 0.73. Interactive voice response administration correlated 0.81 to 0.86 with clinician interviews. |
| ***Demographics*** | Date of birth, gender, country of birth; gender identity (M/F/neither/both); sexual orientation, race/ethnicity; birthplace, parents' occupation, educational attainment, topic of study, year of academic study, level of study UG/PG/apprenticeship. | |
| ***Educational Achievement*** | Academic outcomes from students either via self-report or consent to access student records. | |

## 10.3 Timeframe for Administration of Demographic and Outcome Measures

**Table 11 Outcome measures timeframe**

| | **Time Period** | | | |
|---|---|---|---|---|
| **Outcome Measure** | **Screening** | **Baseline (Treatment Start)** | **6 Weeks Post Baseline (Treatment End)** | **12 Week Post Baseline** |
| **Demographic** | **X** | | | |
| **Brief Resiliency Scale** | | **X** | **X** | **X** |
| **PHQ9** | **X** | **X** | **X** | **X** |
| **GAD7** | **X** | **X** | **X** | **X** |
| **WSAS** | **X** | **X** | **X** | **X** |
| **Feasibility Outcomes** | | | | **X** |

## 10.4 Primary endpoint/outcome

The primary endpoint of the trial is at 12 weeks post baseline.

## 10.5 Secondary endpoints

The secondary endpoint is at 6 weeks post baseline (treatment end).

## 10.6 Exploratory endpoints

There are no exploratory endpoints.

# 11 ACCEPTABILITY FOCUS GROUP

## 11.1 Focus group invitation

At the end of treatment (6 weeks post baseline), participants that have received the sbLICBT resiliency intervention will receive an email inviting them to participate in a focus group either online or face-to-face or a combination of both.

A template invitation email for initial response is as follows:

"Dear ,
Many thanks for engaging with the Bounce Back CBT resiliency intervention.

Now the provision of support for the 6 week intervention has ended we'd like to invite you to take part in a focus group that will include a maximum number of 10 students that have taken part in the study. The focus group will last for a maximum of 45 minutes.

The aim of the focus group is to help us gain an understanding regarding your attitudes towards the intervention exploring what you liked and didn't like and any improvements you feel could be made to the written intervention or support offered.

To help us improve the intervention moving forwards, we'd really appreciate it if you would be happy to take part in the focus group.

If you are happy to participate: Please contact the researcher who will be in touch to find a suitable date and time.

If you do not wish to participate: You are not obliged to do so, however it would help us to understand any reasons why to improve and future study. If you are happy to inform us of any reasons, please indicate these to the researcher.

Best wishes,
Researcher Name"

## 11.2 Acceptability Prompts for Focus Group

A template is provided below of potential questions and answers that the students who received the intervention will be asked in order to gain a better understanding of their experiences and how to improve the intervention.

| | | | | |
|---|---|---|---|---|
| 1 | I would really like to know more about your experience of engaging with the intervention. | | | |
| 2 | What did you think about the group session at the start? | | | |
| Liked | | Not Liked | Needed | Improvements |
| 3 | What are your thoughts regarding the written resiliency intervention? | | | |
| Positive features | | Negative features | Improvements-Design | Improvement-Language |
| 4 | What are your thoughts regarding the intervention being available in other formats? | | | |
| On-line computer | | App | Written for online completion | |
| 5 | If at all, what forms of support did you request and what was your experience? | | | |
| 6 | If used email support: | | | |
| Liked | | Not Liked | Style | Improvements |
| 7 | If used face-to-face support: | | | |
| Liked | | Not Liked | Style | Improvements |
| 8 | If support not used, why not? | | | |

## 12. STATISTICS AND DATA ANALYSIS

Statistical/methodological advice sought and provided by Exeter CTU and their statisticians.

### 12.1 Sample size calculation

As a feasibility study with embedded pilot RCT there is no sample size calculation. Rather, data will be used to inform a sample size calculation for any subsequent definitive RCT were the data to demonstrate potential effectiveness.

### 12.2 Planned recruitment rate

Recruitment of 120 participants into the study across two iterations of intervention delivery (Cohort 1=30 SbRI; 30 DLT; Cohort 2=30 SbRI; 30=DLT) will take place over 28 weeks (June 2023 to December 2023) (originally 1/9-22 to 13/3/23 within a single study site (University of Exeter). Recruitment rate within this timeframe represents a feasibility outcome.

### 12.3 Statistical analysis plan

A detailed statistical analysis plan (SAP) is to be produced; the main points of the statistical analysis are summarised here.

### 12.4 Summary of baseline data and flow of patients

The analysis and presentation of the trial will be in accordance with CONSORT guidelines (Schulz et al., 2010). Recruitment, intervention uptake, outcome completion rates and attrition will be reported (with 95% CIs) and shown on a flow diagram.

Premature discontinuation of intervention may be instigated by the participant or investigator. Participants may elect to withdraw from the study if they wish to do so at any time and for any reason (including perceived harms or lack of efficacy of intervention). Researchers may also request that trial intervention be discontinued for reasons of participant safety at any time; such requests will be made to and approved by the PI or an appointed deputy where possible.

Participants will be withdrawn from the study entirely if discovered as ineligible at the time of recruitment. As a self-help psychological intervention, we do not anticipate significant iatrogenic effects or side-effects requiring individual discontinuation. Participants who elect to discontinue their allocated intervention will be requested to continue to provide outcome data. If a participant wishes to withdraw from the study entirely (and not provide further follow-up data) we will ask them if they are happy to allow us to retain the data already provided to the trial; if the participant does not consent to retention of data, the data will be destroyed.

### 12.5 Primary analysis

Outcomes related to study feasibility and intervention acceptability (see **Table 9** and **Table 10**).

### 12.6 Secondary analyses

#### 12.6.1 12 week post baseline follow-up comparison

Primary (BRS) and secondary (PHQ-9; GAD-7, WSAS) outcomes will be compared at 12 week follow-up using the statistical approach outlined above.

### 12.6.2 Repeated measures comparison including all timepoints

Secondary outcomes (resilience, anxiety, depression, work and social adjustment) will be taken at baseline, 6 weeks (treatment duration) and 12 weeks post randomisation. Secondary continuous outcomes will be reported descriptively (mean and standard deviation (SD)) and inferential comparisons will be reported between the two conditions (1) *sbLICBT*; (2) *DTC* to explore potential effect sizes and confidence intervals.

## 12.7 Interim analysis and criteria for the premature termination of the trial

No interim analyses are planned. In order to detect potential harms the study will monitor potential adverse effects. Adverse and serious adverse effects will result in trial discontinuation if there is cumulative evidence that the intervention may cause harm.

## 12.8 Other statistical considerations

Primary analyses will be performed by a statistician who remains blinded to group allocation with analyses presented as such to the investigators. The results will be discussed and interpreted prior to the unblinding of group allocations.

## 13. ADVERSE EVENTS

### 13.1 Participant welfare and safety

There is no known health risk associated with any of the assessments or the sbLICBT self-help intervention. The risk concerning participation in this study is believed to be low. Further, we anticipate that the self-help will reduce vulnerability and the risk for developing poor mental health and improve well-being and resilience. In our experience from previous projects, participants are happy to participate and enjoy the assessment tasks. We will strive to use tasks that the participants experience as motivational and reinforcing whenever possible. This will also ensure a low attrition rate.

Because the trial is enhancing resiliency and prevention of poor mental health, the initial screening process will exclude anyone with history of severe psychiatric disorder and those reporting elevated suicidality. These individuals will be automatically guided towards appropriate information and sources of help. This process means that individuals likely to have significantly increased risk (e.g., for self-harm and suicidality), and/or for whom more intensive psychological and psychiatric treatment is appropriate, will not be included in the study.

Other than the intervention failing to produce an effect, there is nothing in the literature to suggest possible adverse effects of the assessments and interventions for the young people involved. Versions of components within the intervention have been previously used with no detected harmful effect.

As with all psychological interventions, individuals reflect on their difficulties, which can produce temporary increases in distress, but no more than would commonly occur in daily life. Prior work has provided positive feedback on the sbLICBT self-help intervention and indicated enhanced resiliency, with no serious adverse events reported: as such, the intervention within the trial may benefit individual participants. The likeliest outcome for users who do not find the intervention of benefit is their disengagement from it. In addition, all participants receive more intensive monitoring, with processes to identify and direct all relevant participants to potential sources of help.

As part of our policy for addressing risk and prioritising the welfare of participants, participants are provided with links to online support, access to contact the trial team, and automatic signposting to help and guidance if reporting risk (e.g., suicidal thoughts, as indexed in items within outcome measures such as the Patient Health Questionnaire-9, PHQ-9 on the screening or follow-up websites) or levels of symptoms suggesting a need for help within any of the assessments within the cohort study. These messages include general information on the presenting symptom, recommended actions to make themselves safe, and advice to seek medical help, and direct links to relevant national sources of help.

The main indicators of harm will be the completion of questionnaires by the participants at all assessments (baseline, 6 weeks, 12 weeks). Questionnaires will be automatically screened for signs of severe distress (for example, defined as scores above 20 on PHQ-9 for depression or reports of suicidal ideation), with automatic programmed questions following up to ascertain aspects of risk and to automatically provide users with recommended advice and signpost towards help (family doctor, local hospital, relevant charities; e.g., website link to the Samaritans in the UK. Other indicators would be report of worsening symptoms or suicidality in direct contact from participants to the research team. Individuals reporting severe levels of symptoms or meeting diagnostic criteria for depression will be offered guidance to seek appropriate help from their GP/family doctor, occupational health or student well-being service should this seem necessary.

For those who enter the trial and then indicate risk there will be the option to contact a site researcher via e-mail or telephone to seek advice. This advice will include guidance to seek appropriate help from their GP/family doctor, occupational health or student well-being service should this seem necessary. Project researchers will be trained in and provided with a protocol to assess risk and with standard useful responses in these circumstances (see Section 14 on Risk Management). The trial site has a designated senior clinician [clinical psychologist or CBT Therapist] who will be available as a resource to researchers to provide guidance on clinical issues arising from participants either through

standardized measures or contacts initiated by the participant. If the researcher has serious concerns about a participant, where appropriate, after discussion with the clinician, the clinician will contact the participants (by email, telephone) to review the situation, provide guidance and offer to write a referral letter, subject to participant consent. These procedures will be made explicit in all information sheets. Any concerns detected this way will be recorded on a standardised pro forma, a copy which will be sent to the sponsor for the trial. The same process will be activated in response to any concerns raised by participants at other times, either spontaneously or in responses during the assessments.
We will record both serious and non-serious adverse events as defined by the National Research Ethics Service (e.g. deaths; self-harm; serious violent incidents, referral to crisis care or admission to psychiatric hospital) within both groups and report them to the Research Ethics Committee to determine whether events are related to the treatments and to take appropriate action.

### 13.2 Definitions

Standard definitions for adverse events etc are in the table below. Because the current interventions are digital self-help rather than a medicinal product and involve no biological agent, it is not appropriate to define adverse events etc re any untoward medical occurrence – rather as a psychological intervention, appropriate adverse events would include those related to mental state and behaviour:

i) Serious adverse events (SAEs) including death, suicide attempt, self-harm, serious accident or violent incident, referral to crisis care or admission to psychiatric hospital.
ii) Adverse Events (AE) may include significant worsening symptoms of anxiety, worsening symptoms of depression, as operationalized by a reliable deterioration of movement from 'mild' to 'severe' or 'moderate' to 'severe' levels of symptoms on GAD7 or PHQ9 AND a change of ≥4 points on GAD7 or ≥6 points on PHQ9 from baseline assessment to 6 weeks assessment or from 6 weeks assessment to 12 weeks assessment, new instance of self- harm, new instance of suicidality.

The following definitions are therefore adapted in light of this – see ***Table 12***.

**Table 12 Definitions of Events**

| Term | Definition |
|---|---|
| **Adverse Event (AE)** | Standard: Any untoward medical occurrence in a participant to whom a medicinal product has been administered, including occurrences which are not necessarily caused by or related to that product.<br>*Adapted: Any deterioration in mental state or behaviour in a participant to whom the intervention has been administered, including occurrences which are not necessarily caused by or related to the intervention*. |

| | |
|---|---|
| **Adverse Reaction (AR)** | Standard: An untoward and unintended response in a participant to an investigational medicinal product which is related to any dose administered to that participant.<br>The phrase "response to an investigational medicinal product" means that a causal relationship between a trial medication and an AE is at least a reasonable possibility, i.e,. the relationship cannot be ruled out.<br>All cases judged by either the reporting medically qualified professional or the Sponsor as having a reasonable suspected causal relationship to the trial medication qualify as adverse reactions.<br>*Adapted: An untoward and unintended response in a participant to an intervention which is related to any dose of the intervention administered to that participant.*<br>The phrase "response to an intervention" means that a causal relationship between an intervention and an AE is at least a reasonable possibility, i.e. the relationship cannot be ruled out.<br>All cases judged by either the reporting appropriately clinically qualified professional or the Sponsor as having a reasonable suspected causal relationship to the intervention qualify as adverse reactions. |
| **Serious Adverse Event (SAE)** | Standard: A serious adverse event is any untoward occurrence that:<br>• results in death<br>• is life-threatening<br>• requires inpatient hospitalisation or prolongation of existing hospitalisation<br>• results in persistent or significant disability/incapacity<br>• consists of a congenital anomaly or birth defect<br>Other 'important events' may also be considered serious if they jeopardise the participant or require an intervention to prevent one of the above consequences.<br>NOTE: The term "life-threatening" in the definition of "serious" refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe. |
| **Serious Adverse Reaction (SAR)** | Standard: An adverse event that is both serious and, in the opinion of the reporting Investigator, believed with reasonable probability to be due to one of the trial treatments, based on the information provided. |
| **Suspected Unexpected Serious Adverse Reaction (SUSAR)** | Standard: A serious adverse reaction, the nature and severity of which is not consistent with the information about the medicinal product in question set out in the reference safety information:<br>• in the case of a product with a marketing authorisation, this could be in the summary of product characteristics (SmPC) for that product, so long as it is being used within it's licence. If it is being used off label an assessment of the SmPCs suitability will need to be undertaken.<br>• in the case of any other investigational medicinal product, in the investigator's brochure (IB) relating to the trial in question<br>*Adapted: A serious adverse reaction, the nature and severity of which is not consistent with the information about the intervention in question set out in the reference safety information* |

### 13.3 Recording and reporting of SAEs, SARs AND SUSARs

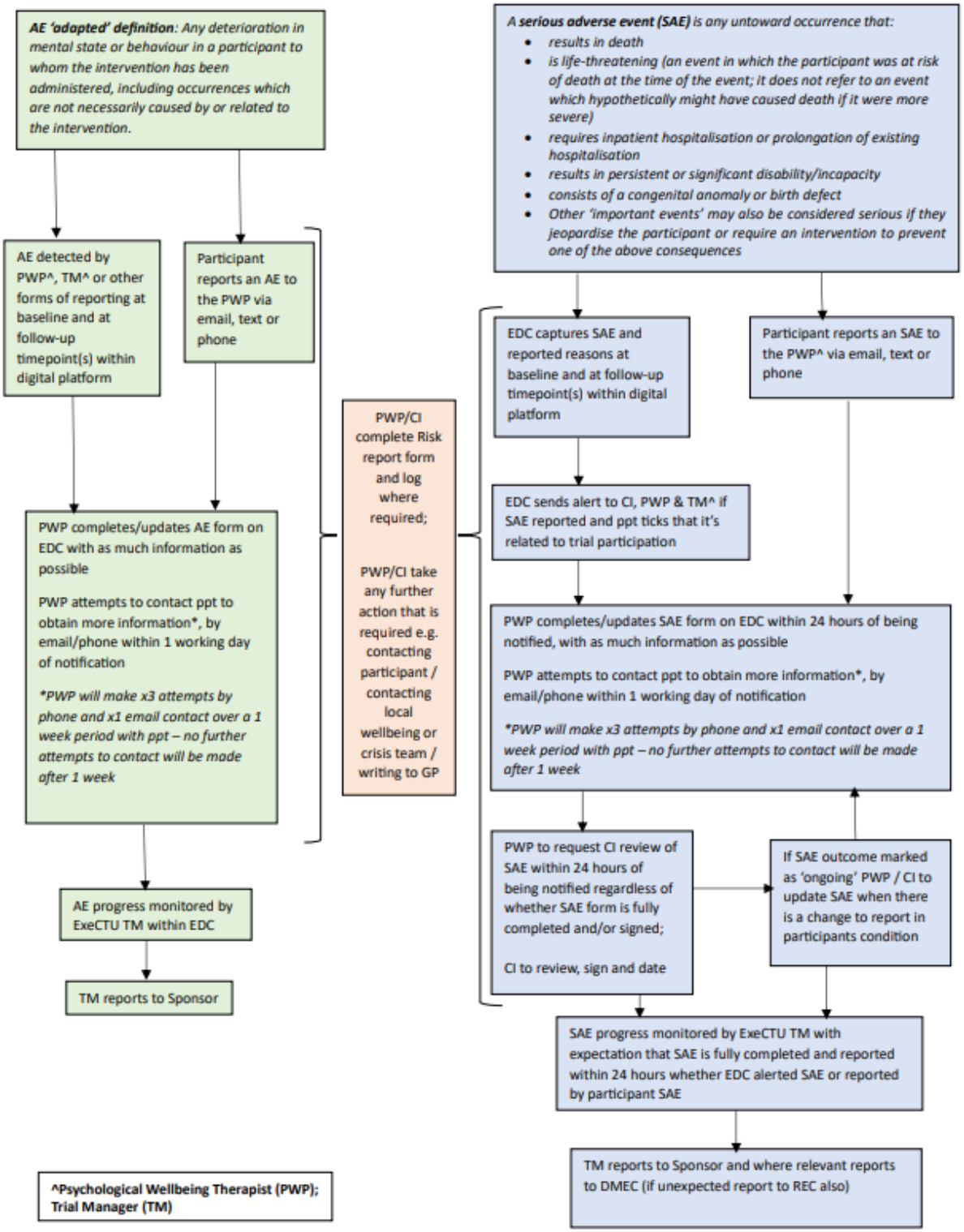
All serious adverse events that are trial or treatment related will be recorded and immediately reported to the Chief Investigator and within 1 working day (24 working hours) to the ExeCTU Trial Manager. If these are also classed as unexpected, they will be reported to the relevant ethics committees.

We will, in line with other complex intervention studies, monitor non-serious adverse events, serious adverse events that are not trial or treatment related, serious deterioration, and active withdrawals from treatment, with specific questions in the follow-up and in response to specific participant-initiated reports. Symptoms of depression or anxiety will not be defined as adverse events unless suicidal ideation, plans or an attempt has been made. The reporting period for all events and reactions will be from referral to 12weeks post baseline follow-up. Data on any adverse events will be collected by a member of the research team at each assessment and entered directly into the EDC.

The SAE form will capture the following data:

- Date and time of onset
- Date and time investigator became aware
- SAE category
    - Death i.e. (homicide, suicide, accident, illness, all appropriate options) etc.)
    - Life threatening i.e. (suicide attempt, serious assault, self- harm)
    - Hospitalisation or prolongation of existing hospitalisation or referral to crisis team
    - Persistent or significant disability or incapacity i.e. (include development of problematic substance/ alcohol abuse; onset of new Axis I disorder)
    - Congenital anomaly or birth defect
    - Other i.e. (potentially dependent life events, e.g. job loss divorce)
- The intensity will be specified as mild, moderate or severe
- The SAE will be determined as intermittent or continuous
- The SAE will be determined as expected or unexpected
- The SAE outcome will be determined as resolved with a date provided, resolved with sequelae, ongoing (follow ups to the SAE will be provided when there is a change to report in participants condition) or died (if died the cause of death will be specified)
- The SAE relationship to the study or trial procedures will be determined as not related, unlikely to be related, possibly related, definitely related or unknown
- A detailed description of the event will be provided and this field will also be used to document the dates and number of attempts made to contact a participant by phone and/or email in order to obtain details about the event, the discussion that took place during any successful phone calls/emails and subsequent actions agreed or discussed between the participant and researcher/clinician
- The CI will report on their assessment of the implications (if any) for the safety of study participants and how they will address the implications
- The form must be signed and dated by the CI

## Figure 2 Safety reporting flow chart



### 13.4 Responsibilities

Researchers at central site (University of Exeter) to check for SAEs, AEs and ARs when participants complete treatment or at follow-up, potentially in response to automated feedback from website.

Chief Investigator (CI) is responsible via liaison with research team at central site for:

1. Ensuring that all SAEs are recorded in EDC and reported to the ExeCTU Trial Manager within 24 working hours / 1 working day of becoming aware of the event and provide further follow-up information as soon as available.
2. Ensuring that SAEs are chased with ExeCTU Trial Manager if a record of receipt is not received within 2 working days of initial reporting.
3. Ensuring that AEs and ARs are recorded and reported to the ExeCTU Trial Manager in line with the requirements of the protocol.
4. Immediate review of all SUSARs.
5. Review of specific SAEs and SARs in accordance with the trial risk assessment and protocol as detailed in the Trial Monitoring Plan.

Sponsor (NB where relevant these can be delegated to CI and trial manager) is responsible for:

1. Central data monitoring and verification of AEs, ARs, SAEs, SARs and SUSARs according to the trial protocol within the database (EDC).
2. Reporting safety information to the CI, delegate or independent clinical reviewer for the ongoing assessment of the risk / benefit according to the Trial Monitoring Plan.
3. Reporting SAEs that are related to the trial and unexpected, by email to the research ethics committee.
4. Reporting SAEs that are related to the trial and unexpected, by email to the research ethics committee.
5. Reporting safety information to the independent oversight committees identified for the trial (Data Monitoring Ethics Committee (DMEC) and / or Trial Steering Committee (TSC)) according to the Trial Monitoring Plan.
6. Expedited reporting of SUSARs to the Competent Authority (MHRA in UK) and REC within required timelines.
7. Notifying Investigators of SUSARs that occur within the trial.
8. Preparing standard tables and other relevant information in collaboration with the CI and ensuring timely submission to the MHRA and REC.

### 13.5 Notification of deaths

All deaths will be reported to the ExeCTU Trial Manager who will report to the Sponsor, irrespective of whether the death is related to the trial or an unrelated event. If the event is unrelated to the feasibility trial then this will be reported to the sponsor within one week, and if it thought to be related to the trial the report will be submitted within 2 working days.

### 13.6 Reporting urgent safety measures

If any urgent safety measures are taken the CI/Trial Manager shall immediately and in any event no later than 3 days from the date the measures are taken, give written notice to the relevant ethics committee, Sponsor and other appropriate bodies where relevant (e.g. MHRA) of the measures taken and the circumstances giving rise to those measures.

### 13.7 The type and duration of the follow-up of participants after adverse reactions

In the event of any reported adverse reaction to the intervention the participant will be contacted by the site researcher or clinician within 2 working days to review status and options.

# 14. RISK MANAGEMENT

## 14.1 Risk Assessment and Reporting

In the assessments we explicitly ask and screen for symptoms of distress, wellbeing and poor mental health (including symptoms of depression, suicidal risk). Whether meeting exclusion criteria at baseline or indicating risk at follow up, participants will be provided with automatic feedback with suggested sources of help such as the recommendation to consult their GP or weblinks or phone numbers for national services.

### 14.1.1 Risk management during pre-screening

In response to recommendations from our ethical review boards we have now added a pre-screening section to our assessment to allow those with experience of, or symptoms of depression to access help pages linking to sources of support as soon as possible. Participants are given the following automated paragraph and options:

**Pre-screening website automated message:**

This study aims to examine the effectiveness of a written strength-based intervention based on Cognitive Behavioural Therapy to enhance resiliency in young people that are currently well. If you are currently struggling with depression, traumatic experiences, or suicidal thoughts then the trial would not be right for you and specialist help would be the best option. If these issues are affecting you now then we would urge you to reach out to family, friends, or your family doctor/general practitioner. Click the relevant button to below for some links to relevant helpful information and support services available to you.

- I would like to learn what depression is
- I am having suicidal thoughts at the moment
- I have depression now
- I have experienced a traumatic experience in the last month
- I do not have depression or experienced a traumatic experience in the last month and would like to take part in the trial
- I do not want to take part

Each of the options is linked to help pages. If participants access the help pages on current depression, or risk then they are excluded from the trial. Their contact details have not been taken at that stage so they cannot be contacted.

### 14.1.2 Risk management In Trial

For those taking part in the trial there is the option for seeking more information from the study team and where risk is indicated a trial clinician may contact them directly.
Each occurrence of elevated symptomatology (PHQ9>20) or risk (PHQ9-Q9=>1) will be logged by the electronic system and the relevant research officer, Trial Manager and CI informed.

We note that the nature of the high level of confidentiality means that we do not have relevant GP or family doctor details for participants, unless these are provided voluntarily in additional communications, and thus of the main management pathways for detecting a clinical presentation, the default response is direct information disclosure to the participant of a potential clinical issue with appropriate advice and signposting. Transmission of the collected information to the GP will not be routinely possible and requesting this information a priori would negate the ethical and recruitment benefits of pseudo-anonymity and confidentiality for participants. Nonetheless, when we alert a

young person that they are having symptoms consistent with clinical cut-offs the clinician can offer to contact their primary care doctor on their behalf if they volunteer the necessary contact information.

The third option ("right not to know") is not deemed appropriate in this context when applied to the individual young person: since the likeliest presentation (elevated symptoms of depression, distress and stress) is treatable. Based on recent recommendations, our default policy is to inform young people of the possibility of them having these conditions and to recommend they seek help. This is to prioritise their welfare.

## 14.2 Preventing Abuse of Participants and Risk Analysis

Our risk analysis indicates potential theoretical risks and opportunities for abuse of the research findings and of participants within the study including psychological harms (e.g., distress), invasion of privacy (e.g., intrusion into private affairs, public disclosure of embarrassing private information, publicity that puts the individual in a false light to the public, or appropriation of an individual's name or picture for personal/commercial advantage), loss of confidentiality (personal data becoming public through error or thorough deliberate hacking), and social harms (e.g., embarrassment, stigmatisation). The risk analysis indicates that the likelihood of these risks occurring is relatively low although any potential impact for participants would be high, and, as such, we will enact a detailed participant risk register and update it regularly through the project. Multiple steps and processes will be put into place to mitigate and minimise these risks including (a) explaining potential risks in the information sheet; (b) the welfare procedures described above to minimise participant distress; (c) high levels of security and the use of privacy by design protocols for the app and database; (d) a privacy impact assessment; (e) the emphasis on confidentiality in the project and the separation of collected data from personal identifiers; (f) the use of a code of conduct for all researchers.

In this trial no medical care is provided regardless of the level of risk presented. This is because this trial is seeking to enhance resiliency in a group that we are a study aiming to enhance resiliency in a self-help intervention for people with no current risk or have experienced a traumatic episode in the last month. Participants are advised of this on the information sheets and sign the section on the consent form to confirm that they understand this.

## 14.3 Identifying Suicide Risk

These are 3 ways that that a recruit or participant could indicate risk to the research team (1) during a screening/follow-up assessment, (2) raised with the trial PWP providing 'on demand' support (3) providing to the facilitator or in direct contact with a trial researcher by phone, text or email.

### 14.3.1 EDC Website at Screening

A recruit may indicate risk on website during the screening phase of the baseline assessment in response to questions about suicidality. If the participant scores 1-3 on question 9 of the PHQ9, then further questions to assess risk will automatically be presented.

*PHQ9-Q9*
*Over the last two weeks, how often have you been bothered by any of the following problems? Thoughts that you would be better off dead, or of hurting yourself in some way?*
*Those scores would represent the answers several days (1), more than half the days (2) and nearly every day (3)*
The further risk questions which will automatically be asked:
*R1 In the last 2 weeks have you been experiencing regular thoughts about suicide?*
*R2 In the last 2 weeks have you had any intention to hurt or kill yourself?*

*R3 In the last 2 weeks have you made any plans to harm yourself or end your life?*

If the recruit answers yes to any of those questions then they would be excluded from the trial and would be automatically presented with the following risk page:

**EDC Screening Website suicide risk automated message:**

**"Your responses to these questions suggest you have been thinking about suicide or about hurting yourself.**
These kinds of thoughts can vary a lot. This may have just been a brief passing thought or reflect a sense of feeling trapped, but without any intention to do anything. These thoughts are relatively common and not that unusual in people who feel stressed. If you would like support with these thoughts, please contact your GP or relevant medical professional.

**If you feel at high risk to yourself or others, please contact your GP immediately.**
**You can contact your GP** using the normal telephone number for your GP practice. If the surgery is not open, you will either be re-directed automatically to the out-of-hours GP service or you will be given another number to call. You can also **phone 111 to access the NHS 111 service**, which provides access to local NHS healthcare services in England, and is available 24 hours a day, 365 days a year.
However, you may have been thinking about your death a lot, having persistent thoughts about killing yourself, experiencing suicidal intentions and urges, or be making plans to end your life. In any of these cases or if you have any other thoughts of suicide, we strongly recommend that you contact your general practitioner or family doctor **RIGHT AWAY** for advice and tell them how you are feeling
**If you don't think you can stay safe**, please go to the nearest hospital accident and emergency room.
If none of these options are available, please contact a family member or a trusted friend, so that you won't be alone right now. It's important to seek out the company of people who can support you and who will help to keep you safe.

Try to commit to a plan of action that does not involve suicide. If you have items that maybe dangerous for you at home, please consider giving them to a trusted friend, neighbour, the police or a pharmacist for safe keeping until you feel stronger. Try to minimise the use of alcohol or illicit drugs, as using these substances are likely to make your recovery harder. It can also be helpful to think about your faith, loved ones, family and pets. It is important to remember that these feelings and urges do pass, and when individuals feel better, they are glad that they did not act on them. There are effective treatments that can help, and there is no need to struggle alone. Talking to people who understand can make it much easier to manage your symptoms so do please call one of the specialist helplines above. There may be reasons for hope that you have yet to consider. Sometimes the smallest reasons for living can get you through a difficult time. Having thoughts of suicide is nothing to be ashamed of and we encourage you to seek help.

Because the study is focused on enhancing resiliency and preventing poor mental health in the future, rather than treating current difficulties, this study is not suitable for you. The written resiliency intervention has not been designed to help with these difficulties so we are sorry to say that taking part in the study would not be in your best interests at this time. Thank you for your interest.

**We strongly recommend contacting your GP or family doctor as the best person to decide what help you need**.

In addition to your GP or if you don't feel that you can talk to your GP, there are many useful services and useful sources of support.

We hope that you find one or more of the following helpful:

- **Papyrus 0800 068 4141 or text: 07786 209697** offers National support to young people up to age 35 who are feeling suicidal. (Monday-Friday 10:00am-5:00pm and 7:00pm-10:00pm; 2:00pm-5:00pm on weekends, pat@papyrus-uk.org
- The **Samaritans 08457 90 90 90** Freephone (UK and Republic of Ireland): 116 123 (24 hours) offer a confidential service so you can talk about your feelings, you can contact them at www.samaritans.org, Email: jo@samaritans.org
- **SANE** offers support to anyone coping with mental illness, including concerned relatives or friends. The SANE helpline **0845 767 8000** is available 7 days a week from 6.pm-11 pm
- **Maytree** is a registered charity supporting people in suicidal crisis and is open for calls and emails 24 hours a day. **– 020 7263 7070,** maytree@maytree.org.uk
- **Young Minds Crisis Messenger** provides free, 24/7 crisis support across the UK if you are experiencing a mental health crisis. If you need urgent help text YM to 85258. Texts are free from EE, O2, Vodafone, 3, Virgin Mobile, BT Mobile, GiffGaff, Tesco Mobile and Telecom Plus.
- **CALM 0800 58 58 58** (Daily 17:00-midnight) Offers support to young men in the UK who are down or in a crisis, www.thecalmzone.net
- **The Mix**, Freephone: 0808 808 4994 (13:00-23:00 daily), If you're under 25 you can talk to The Mix for free on the phone, by email or on their webchat. You can also use their phone counselling service, or get more information on support services you might need. www.themix.org.uk
- There are a series of NHS self-help guides which can be found here https://web.ntw.nhs.uk/selfhelp/
- There are more guides and online courses here: https://www.cci.health.wa.gov.au/Resources/Looking-After-Yourself

If you would like further advice on these issues from the team, you can contact us by submitting the form below to send an email to the research team.
We note that the research team are not clinicians and cannot provide therapy. However, we can guide you in accessing help, for example, by contacting your GP, which is why we ask for GP details. The team are only available during normal working hours, Monday to Friday and may take 1 or 2 working days to respond.

FORM TO SUBMIT

**Name**
**Address**
**Phone number**
**GP Name**
**GP Phone number**
**GP Address**

### 14.3.2 Assessment Website at Follow-up (6 and 12 weeks)

A recruit may indicate risk on the assessment website in follow-up assessments in response to questions about suicidality. If the participant scores 1-3 on question 9 of the PHQ9, then further questions to assess risk will automatically be presented.

*PHQ9; Q9*
*Over the last two weeks, how often have you been bothered by any of the following problems? Thoughts that you would be better off dead, or of hurting yourself in some way?*
*Those scores would represent the answers several days (1), more than half the days (2) and nearly every day (3)*
The further risk questions which will automatically be asked:
*R1 In the last 2 weeks have you been experiencing regular thoughts about suicide?*
*R2 In the last 2 weeks have you had any intention to hurt or kill yourself?*
*R3 In the last 2 weeks have you made any plans to harm yourself or end your life?*

If the participant answers yes to any of those questions then they would be automatically presented with the following risk page:

**Follow up Website Automated Risk Message:**

**"Your responses to these questions suggest you have been thinking about suicide or about hurting yourself.**

These kinds of thoughts can vary a lot. This may have just been a brief passing thought or reflect a sense of feeling trapped, but without any intention to do anything. These thoughts are relatively common and not that unusual in people who feel stressed. If you would like support with these thoughts, please contact your GP or relevant medical professional;

**If you feel at high risk to yourself or others, please contact your GP immediately.**
**You can contact your GP** using the normal telephone number for your GP practice. If the surgery is not open, you will either be re-directed automatically to the out-of-hours GP service or you will be given another number to call. You can also **phone 111 to access the NHS 111 service**, which provides access to local NHS healthcare services in England, and is available 24 hours a day, 365 days a year.
However, you may have been thinking about your death a lot, having persistent thoughts about killing yourself, experiencing suicidal intentions and urges, or be making plans to end your life. In any of these cases or if you have any other thoughts of suicide, we strongly recommend that you contact your general practitioner or family doctor RIGHT AWAY for advice and tell them how you are feeling
**If you don't think you can stay safe**, please go to the nearest hospital accident and emergency room. If none of these options are available, please contact a family member or a trusted friend, so that you won't be alone right now. It's important to seek out the company of people who can support you and who will help to keep you safe.

Try to commit to a plan of action that does not involve suicide. If you have items that maybe dangerous for you at home, please consider giving them to a trusted friend, neighbour, the police or a pharmacist for safe keeping until you feel stronger. Try to minimise the use of alcohol or illicit drugs, as using these substances are likely to make your recovery harder. It can also be helpful to think about your faith, loved ones, family and pets. It is important to remember that these feelings and urges do pass, and when individuals feel better, they are glad that they did not act on them. There are effective treatments that can help, and there is no need to struggle alone. Talking to people who understand can make it much easier to manage your symptoms so do please call one of the specialist helplines above. There may be reasons for hope that you have yet to consider. Sometimes the smallest reasons

for living can get you through a difficult time. Having thoughts of suicide is nothing to be ashamed of and we encourage you to seek help.

**We strongly recommend contacting your GP or family doctor as the best person to decide what help you need.**

In addition to your GP or if you don't feel that you can talk to your GP, there are many useful services and useful sources of support.

We hope that you find one or more of the following helpful:

- **Papyrus 0800 068 4141 or text: 07786 209697** offers National support to young people up to age 35 who are feeling suicidal. (Monday-Friday 10:00am-5:00pm and 7:00pm-10:00pm; 2:00pm-5:00pm on weekends, pat@papyrus-uk.org
- The **Samaritans 08457 90 90 90** Freephone (UK and Republic of Ireland): 116 123 (24 hours),offer a confidential service so you can talk about your feelings, you can contact them at www.samaritans.org, Email: jo@samaritans.org
- **SANE** offers support to anyone coping with mental illness, including concerned relatives or friends. The SANE helpline **0845 767 8000** is available 7 days a week from 6.pm-11 pm
- **Maytree** is a registered charity supporting people in suicidal crisis and is open for calls and emails 24 hours a day. **– 020 7263 7070,** maytree@maytree.org.uk
- **Young Minds Crisis Messenger** provides free, 24/7 crisis support across the UK if you are experiencing a mental health crisis. If you need urgent help text YM to 85258. Texts are free from EE, O2, Vodafone, 3, Virgin Mobile, BT Mobile, GiffGaff, Tesco Mobile and Telecom Plus.
- **CALM 0800 58 58 58** (Daily 17:00-midnight) Offers support to young men in the UK who are down or in a crisis, www.thecalmzone.net
- **The Mix**, Freephone: 0808 808 4994 (13:00-23:00 daily), If you're under 25 you can talk to The Mix for free on the phone, by email or on their webchat. You can also use their phone counselling service, or get more information on support services you might need. www.themix.org.uk

If you would like further advice on these issues from the team, you can contact us by submitting the form below to send an email.
We note that the research team are not clinicians and cannot provide therapy. However, we can guide you in accessing help, for example, by contacting your GP, which is why we ask for GP details. The team are only available during normal working hours, Monday to Friday and may take 1 or 2 working days to respond.

FORM TO SUBMIT

**Name**
**Address**
**Phone number**
**GP Name**
**GP Phone number**
**GP Address**

In the event that a participant indicates suicide risk at follow up and this screen is displayed, an automated report/record from the website will be sent to the therapists and chief investigator and will be logged by them and the trial manager. The record will show the trial number and the answers to the 3 risk questions (e.g., R1=Y, R2=N, R3=N). This data will monitor frequency of suicidality across the trial arms.

### 14.4 Participants excluded at screening with current depression (without risk)

If a participant reports current depression at screenin, but then does not report current risk then they are ineligible for the resiliency trial.

The screening website will automatically provide them with the following information if they meet criteria for current depression:

**Screening Website Automated message for depression:**

**"Your responses to these questions suggest that within the last month, your overall mood has been low for at least 2 weeks and has had a negative effect on your life. It may be that you are currently experiencing an episode of depression or going through a period of stress or loss.**

This trial is focused on enhancing resiliency in young adults that are not currently unwell. Unfortunately, the current study is not suitable for anyone who is currently depressed. Thank you for your interest.

If you currently are having problems with the symptoms of depression then **we strongly recommend that you talk to your general practitioner, family doctor or a mental health professional** about your difficulties, as he or she may be able to find ways to help you to improve your mood and handle life's difficulties better.

If you have not had a health check recently that may also be worth doing so. If you have a diagnosis of depression, please make sure that you follow your treatment regime and consult with the medical professionals involved in your care.

**You can contact your GP** using the normal telephone number for your GP practice. If the surgery is not open, you will either be re-directed automatically to the out-of-hours GP service or you will be given another number to call. You can also **phone 111 to access the NHS 111 service**, which provides access to local NHS healthcare services in England, and is available 24 hours a day, 365 days a year.

As well as your GP, there are many other services available who are really experienced at helping people with your symptoms:

Here are some useful websites that you access directly:

- **Students against depression** is a website by students, for students offering information, guidance and resources to those affected by low mood, depression and suicidal thinking. Alongside clinically-validated information and resources it presents the experiences, strategies and advice of students themselves – after all, who better to speak to their peers about how depression can be overcome? https://www.studentsagainstdepression.org/
- **YoungMinds** are there to make sure all young people get the best possible mental health support and have the resilience to overcome life's difficulties. They provide lots of resources to help with young person's mental health: https://youngminds.org.uk/find-help/
- **Mind** The Mental Health Charity provide information, advice, and support to empower anyone experiencing a mental health problem. They provide information about mental health problems and potential treatments as well as tips for everyday living. https://www.mind.org.uk/
    - **For info about depression:** https://www.mind.org.uk/information-support/types-of-mental-health-problems/depression/#.XGQRn1X7SUk
    - **For apps to help with your mental health and wellbeing:** https://www.mindcharity.co.uk/advice-information/how-to-look-after-your-mental-health/apps-for-wellbeing-and-mental-health/
- **Rethink Mental Illness** Provide expert advice and information to everyone affected by mental health problems, and provide services and groups; including resources specific to young people https://www.rethink.org/living-with-mental-illness/young-people

- Toolkit for young people with questions or worries about their mental health: https://www.rethink.org/media/1020652/ResourceFinal.pdf

**There are a series of NHS self-help guides which can be found here** https://web.ntw.nhs.uk/selfhelp/

- **There are more guides and online courses here:** https://www.cci.health.wa.gov.au/Resources/Looking-After-Yourself

**Helplines**

Alternatively, here are helplines you can ring to talk to someone about what you're going through:

- **Papyrus 0800 068 4141 or text: 07786 209697** offers National support to young people up to age 35 who are feeling suicidal. (Monday-Friday 10:00am-5:00pm and 7:00pm-10:00pm; 2:00pm-5:00pm on weekends, pat@papyrus-uk.org
- The **Samaritans 08457 90 90 90** Freephone (UK and Republic of Ireland): 116 123 (24 hours),offer a confidential service so you can talk about your feelings, you can contact them at www.samaritans.org, Email: jo@samaritans.org
- **SANE** offers support to anyone coping with mental illness, including concerned relatives or friends. The SANE helpline **0845 767 8000** is available 7 days a week from 6.pm-11 pm
- **Maytree** is a registered charity supporting people in suicidal crisis and is open for calls and emails 24 hours a day. **– 020 7263 7070,** maytree@maytree.org.uk
- **Young Minds Crisis Messenger** provides free, 24/7 crisis support across the UK if you are experiencing a mental health crisis. If you need urgent help text YM to 85258. Texts are free from EE, O2, Vodafone, 3, Virgin Mobile, BT Mobile, GiffGaff, Tesco Mobile and Telecom Plus.
- **CALM 0800 58 58 58** (Daily 17:00-midnight) Offers support to young men in the UK who are down or in a crisis, www.thecalmzone.net
- **The Mix**, Freephone: 0808 808 4994 (13:00-23:00 daily), If you're under 25 you can talk to The Mix for free on the phone, by email or on their webchat. You can also use their phone counselling service, or get more information on support services you might need. www.themix.org.uk

Talking to people who understand can make it much easier to manage your symptoms so **please do call your GP or one of the specialist helplines above**.

**14.5 For participants reporting significant levels of depression at any of the follow-up assessments (defined as PHQ-9 score >20)**

The follow-up website will automatically provide them with the following information:

**Follow-up Website Automated message for depression:**

**"Your responses to these questions suggest that within the last month, your overall mood has been low for at least 2 weeks and has had a negative effect on your life. It may be that you are currently experiencing an episode of depression or going through a period of stress or loss.**
If you currently are having problems with the symptoms of depression then **we strongly recommend that you talk to your general practitioner, family doctor or a mental health professional** about your difficulties, as he or she may be able to find ways to help you to improve your mood and handle life's difficulties better.
If you have not had a health check recently that may also be worth doing so. If you have a diagnosis of depression, please make sure that you follow your treatment regime and consult with the medical professionals involved in your care.
**You can contact your GP** using the normal telephone number for your GP practice. If the surgery is not open, you will either be re-directed automatically to the out-of-hours GP service or you will be given another number to call. You can also **phone 111 to access the NHS 111 service**, which provides access to local NHS healthcare services in England, and is available 24 hours a day, 365 days a year.

As well as your GP, there are many other services available who are really experienced at helping people with your symptoms:

Here are some useful websites that you access directly:

- **Students against depression** is a website by students, for students offering information, guidance and resources to those affected by low mood, depression and suicidal thinking. Alongside clinically-validated information and resources it presents the experiences, strategies and advice of students themselves – after all, who better to speak to their peers about how depression can be overcome? https://www.studentsagainstdepression.org/
- **YoungMinds** are there to make sure all young people get the best possible mental health support and have the resilience to overcome life's difficulties. They provide lots of resources to help with young person's mental health: https://youngminds.org.uk/find-help/
- **Mind** The Mental Health Charity provide information, advice, and support to empower anyone experiencing a mental health problem. They provide information about mental health problems and potential treatments as well as tips for everyday living. https://www.mind.org.uk/
    - **For info about depression:** https://www.mind.org.uk/information-support/types-of-mental-health-problems/depression/#.XGQRn1X7SUk
    - **For apps to help with your mental health and wellbeing:** https://www.mindcharity.co.uk/advice-information/how-to-look-after-your-mental-health/apps-for-wellbeing-and-mental-health/
- **Rethink Mental Illness** Provide expert advice and information to everyone affected by mental health problems, and provide services and groups; including resources specific to young people https://www.rethink.org/living-with-mental-illness/young-people
    - Toolkit for young people with questions or worries about their mental health: https://www.rethink.org/media/1020652/ResourceFinal.pdf

- **There are a series of NHS self-help guides which can be found here** https://web.ntw.nhs.uk/selfhelp/
- **There are more guides and online courses here:** https://www.cci.health.wa.gov.au/Resources/Looking-After-Yourself

**Helplines**

Alternatively, here are helplines you can ring to talk to someone about what you're going through:

- **Papyrus 0800 068 4141 or text: 07786 209697** offers National support to young people up to age 35 who are feeling suicidal. (Monday-Friday 10:00am-5:00pm and 7:00pm-10:00pm; 2:00pm-5:00pm on weekends, pat@papyrus-uk.org
- The **Samaritans 08457 90 90 90** Freephone (UK and Republic of Ireland): 116 123 (24 hours),offer a confidential service so you can talk about your feelings, you can contact them at www.samaritans.org, Email: jo@samaritans.org
- **SANE** offers support to anyone coping with mental illness, including concerned relatives or friends. The SANE helpline **0845 767 8000** is available 7 days a week from 6.pm-11 pm
- **Maytree** is a registered charity supporting people in suicidal crisis and is open for calls and emails 24 hours a day. **– 020 7263 7070,** maytree@maytree.org.uk
- **Young Minds Crisis Messenger** provides free, 24/7 crisis support across the UK if you are experiencing a mental health crisis. If you need urgent help text YM to 85258. Texts are free from EE, O2, Vodafone, 3, Virgin Mobile, BT Mobile, GiffGaff, Tesco Mobile and Telecom Plus.
- **CALM 0800 58 58 58** (Daily 17:00-midnight) Offers support to young men in the UK who are down or in a crisis, www.thecalmzone.net
- **The Mix**, Freephone: 0808 808 4994 (13:00-23:00 daily), If you're under 25 you can talk to The Mix for free on the phone, by email or on their webchat. You can also use their phone counselling service, or get more information on support services you might need. www.themix.org.uk

Talking to people who understand can make it much easier to manage your symptoms so **please do call your GP or one of the specialist helplines above**.

### 14.6 Exclusions- Bipolar and Psychosis

If a potential recruit is excluded on the basis of a self-reporting at the screening questionnaire a previous diagnosis of Bipolar disorder or psychosis then would be automatically provided with the following information:

**Screening website automated message for bi-polar disorder:**

"**You have reported that you have previously received a diagnosis of either bipolar disorder or psychosis.**
Because this study is focused on enhancing resiliency and preventing poor mental health in the future, rather than treating current difficulties, the current study is not suitable for you at this time. The resiliency treatment has not been designed to help with these difficulties so we are sorry to say that taking part in the study would not be in your best interests at this time. Thank you for your interest.

**Your GP or relevant medical professional is the best person to decide what help you need.**

**You can contact your GP** using the normal telephone number for your GP practice. If the surgery is not open, you will either be re-directed automatically to the out-of-hours GP service or you will be given another number to call. You can also **phone 111 to access the NHS 111 service**, which provides access to local NHS healthcare services in England, and is available 24 hours a day, 365 days a year.

Alongside your GP, there are other services available to you to provide information and support:

Useful **WEBSITES** that you can access directly below include:

- **YoungMinds** are there to make sure all young people get the best possible mental health support and have the resilience to overcome life's difficulties. They provide lots of resources to help with young person's mental health: https://youngminds.org.uk/find-help/
- **Mind** The Mental Health Charity provide information, advice, and support to empower anyone experiencing a mental health problem. They provide information about mental health problems and potential treatments as well as tips for everyday living. https://www.mind.org.uk/
    - **For bipolar disorder:** https://www.mind.org.uk/information-support/types-of-mental-health-problems/bipolar-disorder/about-bipolar-disorder/?o=1142#.XGQJJVX7SUk
    - **For psychosis:** https://www.mind.org.uk/information-support/types-of-mental-health-problems/psychosis/#.XGQI_lX7SUk
    - **For schizophrenia**: https://www.mind.org.uk/information-support/types-of-mental-health-problems/schizophrenia/about-schizophrenia/?o=6266#.XGQJQlX7SUk
    - **For apps to help with your wellbeing and mental health:** https://www.mindcharity.co.uk/advice-information/how-to-look-after-your-mental-health/apps-for-wellbeing-and-mental-health/
- **BipolarUK** National charity dedicated to supporting individuals with bipolar, their families and carers. Their websites has information leaflets and links to support, including a peer support line https://www.bipolaruk.org/
- **Rethink Mental Illness**. Provide expert advice and information to everyone affected by mental health problems, and provide services and groups; including resources specific to young people https://www.rethink.org/living-with-mental-illness/young-people
    - **Toolkit for young people with questions or worries about their mental health:** https://www.rethink.org/media/1020652/ResourceFinal.pdf
- **There are a series of NHS self-help guides which can be found here** https://web.ntw.nhs.uk/selfhelp/

- **There are more guides and online courses here:** https://www.cci.health.wa.gov.au/Resources/Looking-After-Yourself

Alternatively, here are **HELPLINES** you can ring to talk to someone about what how you are feeling

- **Papyrus 0800 068 4141 or text: 07786 209697** offers National support to young people up to age 35 who are feeling suicidal. (Monday-Friday 10:00am-5:00pm and 7:00pm-10:00pm; 2:00pm-5:00pm on weekends, pat@papyrus-uk.org
- The **Samaritans 08457 90 90 90** Freephone (UK and Republic of Ireland): 116 123 (24 hours),offer a confidential service so you can talk about your feelings, you can contact them at www.samaritans.org, Email: jo@samaritans.org
- **SANE** offers support to anyone coping with mental illness, including concerned relatives or friends. The SANE helpline **0845 767 8000** is available 7 days a week from 6.pm-11 pm
- **Maytree** is a registered charity supporting people in suicidal crisis and is open for calls and emails 24 hours a day. **– 020 7263 7070,** maytree@maytree.org.uk
- **Young Minds Crisis Messenger** provides free, 24/7 crisis support across the UK if you are experiencing a mental health crisis. If you need urgent help text YM to 85258. Texts are free from EE, O2, Vodafone, 3, Virgin Mobile, BT Mobile, GiffGaff, Tesco Mobile and Telecom Plus.
- **CALM 0800 58 58 58** (Daily 17:00-midnight) Offers support to young men in the UK who are down or in a crisis, www.thecalmzone.net
- **The Mix**, Freephone: 0808 808 4994 (13:00-23:00 daily), If you're under 25 you can talk to The Mix for free on the phone, by email or on their webchat. You can also use their phone counselling service, or get more information on support services you might need. www.themix.org.uk

If you find your symptoms particularly distressing or have thoughts about ending your life then please go to the nearest emergency room, or immediately contact your GP.

Talking to people who understand can make it much easier to manage your symptoms so **please do call your GP or one of the specialist helplines above**.

## 14.7 Risk Assessment and Reporting SOP

All researchers and clinicians that have direct contact (by telephone or email) with recruits or participants will be familiar and trained how to use this SOP and will sign the delegation log to say that this has been done. The purpose of the SOP is to script the contact between researcher and participant so that the risk is assessed.

PIs/supervisors/clinicians (e.g., local psychiatrists or clinical psychologists) will also familiarise themselves with this SOP and provide researchers with their contact details in case the researcher needs advice. When clinical academic staff are away on leave they should ensure appropriate cover is arranged to support researcher with advice on for any risk issues that might arise in their absence. The clinician is available to support and guide the researcher in responding to risk and where requested in communicating and providing guidance to the participant.

## 14.8 Telephone contact

When conducting telephone interviews or providing on-demand telephone support in which risk may be disclosed, the interviewer should establish the telephone number and location of the participant at the start of the call, and clarify the boundaries of confidentiality:

'Hi, is that (name) this is X from the Nurture-U Bounce-Back trial, is now a convenient time to talk?' [or in response to answering a call direct from a participant – at which point we would ask for name and email, so we can identify them]

If yes 'This call is confidential and the only reason I would break that is if I thought you were at risk to yourself or others and it was in your best interests.

We just wanted to give you a call after your message to us in the email you sent / I would like to clarify what you are telling me now on the phone.

Can I just check where you are at the moment? [obtain details of location/address]

*"I see that you've said / you mentioned that……. (examples: if thoughts of death /"what is the point?" / "it might be better if I did not wake up",*

*"Has this gone as far as thinking about harming yourself or killing yourself?" If yes, or if already stated:*

*'These are common thoughts and can vary a lot in their severity and it's important to make sure you are receiving the right kind of support. So I would now like to ask you some more questions that will explore these feelings in a little more depth."*

***INTENTION***

Have you had any intention to hurt or kill yourself? YES OR NO

---

**PLANS**

1 Do you know how you would kill yourself? Yes / No

If **yes – ask for and record** details

2 Have you made any actual plans to end your life? Yes / No

If **yes – ask for and record** details

**ACTIONS**

3. Have you made any actual preparations to kill yourself? Yes / No

If **yes – ask for and record** details

4. Have you ever attempted suicide in the past? Yes / No

If **yes – ask for and record** details

6. **PREVENTION** Is there anything stopping you killing or harming yourself at the moment? Yes / No

If **yes – ask for and record** details

7. Do you feel that there is any immediate danger that you will harm or kill yourself? Yes / No

Ask for and record Details:

***If yes to any of questions 1-4***

- [if yes to 4 only, or yes to 1 only] I can see that things have been very difficult for you, but it seems to me these thoughts about death are not ones you would act on – would this be how you see things? *(if they say yes)* I would advise you to make an appointment to see your GP to talk about these feelings.
- [if any of 1-3] Would you like us to write a letter to your GP letting them know how you are feeling? If yes, please can you give us your permission to do so *(and provide their contact details)*
- [all] I can also email you a list of website and helplines for people that have expertise at helping in just this kind of situation, would that be helpful?

***If yes to 2 and 3 or to 6, request clinical input if not a clinician and say the following***

- I am very concerned about your safety at this moment….
- I am not a clinician, but I would like you to talk to one right now. With your permission *I am going to call the site clinician/your GP to let them know how you are feeling and to arrange for you to receive immediate help/a call back. Can you provide their contact details?*

***In addition, If yes to question 6 [immediate risk]***

- *I think its best that you get emergency support at this time. I am going to call your GP/the emergency services and send them to your location.*

*Keep the participant on the phone while you call the clinician from another number or email.*

If immediate risk is disclosed the interviewer should not hang up if at all possible.
In case contact is lost, the participant should be informed that the interviewer / supervisor will call them back straight away but that if they are unable to make contact the participant's G.P. or the emergency services will be informed. Good practice is to call /use a phone line for participants that (a) is mobile so that researcher can contact clinical supervisor if physically proximal (b) have a second line to contact clinical supervisor (e.g., by text) whilst maintaining conversation with participant.

## 14.9 E-mail contact

In the eventuality that participants send emails to researchers or receiving on-demand e-mail support that indicate potential elevated suicide risk (e.g. talking about death, ending it all, seeing no hope, referring to suicide or self-harm, seeing no way out), then further follow-up steps will be taken, including attempts to respond to the participant to clarify the severity of the risk. These emails will provide guidance and signposting information (replicating the information provided on the automated webpage in response to reporting suicidality on the screening/assessment website) and enquire about risk following the questions above (e.g., asking about suicidal ideation, thoughts, plans, preparation, prevention, means).

An email will be sent to participant, acknowledging their potential distress and thoughts of death and self-harm, including the following questions:

Self Risk Q1 Are you currently experiencing any thoughts about suicide?

Self Risk Q2 Do you have any intention to hurt or kill yourself?

Self Risk Q3 Have you made any current plans to end your life or harm yourself?

Self Risk Q4 Do you have the means to harm yourself or end your life?

A template email for initial response is as follows, to be adapted to directly respond to details and concerns raised in specific email from the participant:

"Dear ,
Thank you for contacting us.

Your email suggested that you might have been having thoughts about harming or killing yourself. These thoughts can vary a lot from person to person. These may have just been brief passing thoughts or reflect a sense of feeling trapped, but without any intention to do anything. These thoughts are relatively common and not that unusual in people who feel stressed.

On the other hand, you may have been thinking about your death a lot, or you may have thought about killing yourself. You may have even have thought about how you might kill yourself or made a plan to end your life. In any of these cases, we strongly urge you to talk to someone about these thoughts, and in particular your GP or family doctor.

It would be useful to know more about the sort of thoughts you are having at the moment.
Are they just thoughts about death? Or are you having thoughts about killing or harming yourself?
If it is the latter, have you made any actual plans to end your life? Have you made any actual preparations to kill yourself? Is there anything stopping you killing or harming yourself at the moment?
I would appreciate you letting me know the answers to these questions, so I can help you as best I can.

If you are having thoughts of ending your life or harming yourself, I **advise you to contact your general practitioner or family doctor or mental health professional as soon as possible** and tell them how you are feeling. If you don't think you can stay safe, please go to the nearest hospital accident and emergency room or contact one of the suicide hotlines at Befrienders.org or Samaritans.org. If none of these options are available, please contact a family member, a trusted friend, or any other trusted person so that you won't be alone right now.

**Throughout the UK, please contact your GP** using the normal telephone number for your GP practice. If the surgery is not open, you will either be re-directed automatically to the out-of-hours GP service

or you will be given another number to call. You can also **phone 111 to access the NHS 111 service**, which provides access to local NHS healthcare services in England, and is available 24 hours a day, 365 days a year. Details for out of hours services and support across the UK can be found in the leaflet on national out-of-hours services which has been attached to this email.

**If you don't think you can stay safe**, please go to the nearest hospital accident and emergency room. If none of these options are available, please contact a family member or a trusted friend, so that you won't be alone right now. If you have already made a plan, as best you can, please try and get rid of the means to harm yourself, whilst keeping yourself safe. It can also be helpful to focus on anything that may stop you from killing or harming yourself at the moment, such as thinking about your faith, loved ones, family and pets. It is important to remember that these feelings and urges do pass, and when individuals feel better, they are glad that they did not act on them. There are effective treatments that can help, and there is no need to struggle alone. Getting help may make it easier to manage your symptoms and to live the kind of life you would like to live.

Best wishes,
Researcher/PWP Providing Support Name"

Similar actions will be taken for email responses as for telephone contacts (see section above). Follow-up emails may be necessary to either further clarify responses to questions, provide further guidance and support, or provide more detailed signposting for help.

### 14.10 Risk register

All risk alerts whether via email or telephone contact will be logged on a risk register with any action taken, by whom and when (see below). Site researchers will follow up on risk alerts within 1 working day using the risk assessment and reporting SOP including responding to participant and registering the action taken. This will need to be logged at each local site and shared centrally with the lead site (Exeter) in an anonymised format.

### 14.11 Action to take after responding to immediate risk:

1. Document action taken on the risk log and a risk report form (see below).
2. Send letter electronically or by post to GP documenting information gathered and action taken.
3. Seek / offer supervision around support and debriefing as appropriate.

Figure 3
**Risk Report Form**

Participant Trial Number

| |
|---|
| *Suicide risk information: [note answers to all questions above re yes/no answers and details]*<br>*Intention:*<br><br>*Plans:*<br><br>*Actions:*<br><br>*Prevention:*<br><br>*Prior attempts:*<br><br>*Immediate risk:*<br><br>*Date reported: ___/___/___* |
| *Additional notes / actions taken:*<br><br>*Date action taken: ___/___/___* |

Researcher / assessor / supporting PWP: _____ Signed: _____ Date: ___/___/___

Supervisor: _____ Signed: _____ Date: ___/___/___

## 15. DISSEMINATION POLICY

There is an overall dissemination policy for the project, within which there is a specific dissemination policy for the trial results, however aspects of the policy may not be applicable depending on the outcome of this Phase II feasibility trial.

Key aspects of the dissemination policy for the trial include:

(i) the Consort Guidelines and checklist are reviewed prior to generating any publications for the trial to ensure they meet the standards required for submission to high quality peer reviewed journals etc. http://www.consort-statement.org/

(ii) Anonymised data arising from the trial is owned by UNEXE as trial lead, lead for trial design, CTU, and trial analysis, and developer of the intervention, managed by UNEXE as the data controller.

(iii) On completion of the trial, the data will be analysed and tabulated and a Final Trial Report prepared, and made publicly available on the trial website and via the funder. This will be published before the end of the grant.

(iv) Our publication policy stipulates that all potential publication plans need to be reviewed by the Project Steering Committee before release of data to coordinate activity between partners, determine appropriate authorship and avoid duplication and replication of effort.

(v) Authorship will be determined on standard criteria (i.e., consistent with the criteria for individually named authors or group authorship such as The International Committee of Medical Journal Editors defined authorship criteria for manuscripts submitted for publication http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html#two) and will require contributions with respect to design of the study, development of paradigms and interventions within the study, involvement in delivery of the trial, data analysis and/or writing up of the paper. Seniority of authorship will be determined by relative contribution on these elements – individuals leading on design, analysis and write-up of papers will have lead authorship, with this typically following pre-allocated lead roles for the work packages in the grant in the first instance, unless deferred. All papers will include a detailed statement of the relevant author contributions following a standard template.

(vi) All publications as well as all tools described in this section will acknowledge funding from the UKRI Adolescence, Developing mind and Mental Health scheme.

(vii) There are plans to notify the participants of the outcome of the trial, through a combination of a specifically designed newsletter, blog, vlog, videos and website, communicated to participants via email and relevant social media on completion of the study.

(viii) It is possible for the participant to specifically request results from their PI and this information be provided after the results had been published.

(ix) The trial protocol, full trial report, anonymised participant level dataset, and statistical code for generating the results will be made publicly available.

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APPENDIX

Appendix 1: Feasibility Outcomes

| **Feasibility Outcomes** | | | |
|---|---|---|---|
| Number of people accessed study web site | | | |
| Number of people complete screening questions | | | |
| Number of people screened out | | If Yes - Reason | Report by demographics |
| Number of people consented | | | Report by demographics |
| Number of people randomised | | | Report by demographics |
| Blinding randomisation maintained | | Yes | No |
| Study arms | | | |
| sbLICBT | Number attended group session | Report by demographics | |
| | Number completed baseline outcome measure | Data completion of each item for each outcome measure | |
| | Number completed end of treatment outcome measures | Data completion of each item for each outcome measure | |
| | Number completed final outcome measures 12-week post baseline | Data completion of each item for each outcome measure | |
| | Number of participants requesting support | Report by demographics | |
| | Number of support episodes requested | | |
| | Number of each type of support episode requested | Face to Face | e-mail |
| DTC | Number completed baseline outcome measure | | |
| | Number completed outcome measures at 6 weeks post baseline | | |
| | Number completed final outcome measures 12-week post baseline | | |
| DTC move to sbLICBT | Number attended group session | Report by demographics | |
| | Number completed baseline outcome measure | Data completion of each item for each outcome measure | Number completed baseline outcome measure |
| | Number completed end of treatment outcome measures | Data completion of each item for each outcome measure | Number completed end of treatment outcome measures |
| | Number completed final outcome measures 12-week post baseline | Data completion of each item for each outcome measure | Number completed final outcome measures 12-week post baseline |
| | Number of participants requesting support | Report by demographics | |
| | Number of support episodes requested | | |
| | Number of each type of support episode requested | Face to Face | e-mail |

Appendix 2: Secondary Outcome Measures

# Brief Resilience Scale (BRS)

| Respond to each statement below by circling <u>one answer per row.</u> | | Strongly Disagree | Disagree | Neutral | Agree | Strongly Agree |
|---|---|---|---|---|---|---|
| BRS 1 | I tend to bounce back quickly after hard times. | 1 | 2 | 3 | 4 | 5 |
| BRS 2 | I have a hard time making it through stressful events. | 5 | 4 | 3 | 2 | 1 |
| BRS 3 | It does not take me long to recover from a stressful event. | 1 | 2 | 3 | 4 | 5 |
| BRS 4 | It is hard for me to snap back when something bad happens. | 5 | 4 | 3 | 2 | 1 |
| BRS 5 | I usually come through difficult times with little trouble. | 1 | 2 | 3 | 4 | 5 |
| BRS 6 | I tend to take a long time to get over setbacks in my life. | 5 | 4 | 3 | 2 | 1 |

**Scoring:** Add the value (1-5) of your responses for all six items, creating a range from 6-30. Divide the sum by the total number of questions answered (6) for your final score.

**Total score:** _____ / 6

**My score:** _____ (average)

| BRS Score | Interpretation |
|---|---|
| 1.00 - 2.99 | Low resilience |
| 3.00 - 4.30 | Normal resilience |
| 4.31 - 5.00 | High resilience |

Smith, B.W., Dalen, J., Wiggins, K., Tooley, E., Christopher, P. and Bernard, J. (2008). The Brief Resilience Scale: Assessing the Ability to Bounce Back. *International Journal of Behavioral Medicine*, 15, 194-200.

# PATIENT HEALTH QUESTIONNAIRE-9 (PHQ-9)

| **Over the last 2 weeks, how often have you been bothered by any of the following problems?** *(Use "✔" to indicate your answer)* | **Not at all** | **Several days** | **More than half the days** | **Nearly every day** |
|---|---|---|---|---|
| **1.** Little interest or pleasure in doing things | 0 | 1 | 2 | 3 |
| **2.** Feeling down, depressed, or hopeless | 0 | 1 | 2 | 3 |
| **3.** Trouble falling or staying asleep, or sleeping too much | 0 | 1 | 2 | 3 |
| **4.** Feeling tired or having little energy | 0 | 1 | 2 | 3 |
| **5.** Poor appetite or overeating | 0 | 1 | 2 | 3 |
| **6.** Feeling bad about yourself — or that you are a failure or have let yourself or your family down | 0 | 1 | 2 | 3 |
| **7.** Trouble concentrating on things, such as reading the newspaper or watching television | 0 | 1 | 2 | 3 |
| **8.** Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual | 0 | 1 | 2 | 3 |
| **9.** Thoughts that you would be better off dead or of hurting yourself in some way | 0 | 1 | 2 | 3 |

**FOR OFFICE CODING** 0 + _____ + _____ + _____

**=Total Score:** _____

## GAD-7

| Over the last 2 weeks, how often have you been bothered by the following problems? *(Use "✔" to indicate your answer)* | Not at all | Several days | More than half the days | Nearly every day |
|---|---|---|---|---|
| **1.** Feeling nervous, anxious or on edge | 0 | 1 | 2 | 3 |
| **2.** Not being able to stop or control worrying | 0 | 1 | 2 | 3 |
| **3.** Worrying too much about different things | 0 | 1 | 2 | 3 |
| **4.** Trouble relaxing | 0 | 1 | 2 | 3 |
| **5.** Being so restless that it is hard to sit still | 0 | 1 | 2 | 3 |
| **6.** Becoming easily annoyed or irritable | 0 | 1 | 2 | 3 |
| **7.** Feeling afraid as if something awful might happen | 0 | 1 | 2 | 3 |

***(For office coding: Total Score T____ = ____ + ____ + ____ )***

# Work and Social Adjustment Scale (WSAS)

Identifier | Date

People's problems sometimes affect their ability to do certain day-to-day tasks in their lives. To rate your problems look at each section and determine on the scale provided how much your problem impairs your ability to carry out the activity. This assessment is not intended to be a diagnosis. If you are concerned about your results in any way, please speak with a qualified health professional.

If you're retired or choose not to have a job for reasons unrelated to your problem, tick here ☐

| | 0 Not at all | 1 | 2 Slightly | 3 | 4 Definitely | 5 | 6 Markedly | 7 | 8 Very severely |
|---|---|---|---|---|---|---|---|---|---|
| 1 | Because of my [problem] my **ability to work** is impaired. '0' means 'not at all impaired' and '8' means very severely impaired to the point I can't work. | | | | | | | | 0 |
| 2 | Because of my [problem] my **home management** (cleaning, tidying, shopping, cooking, looking after home or children, paying bills) is impaired. | | | | | | | | 0 |
| 3 | Because of my [problem] my **social leisure activities** (with other people e.g. parties, bars, clubs, outings, visits, dating, home entertaining) are impaired. | | | | | | | | 0 |
| 4 | Because of my [problem], my **private leisure activities** (done alone, such as reading, gardening, collecting, sewing, walking alone) are impaired. | | | | | | | | 0 |
| 5 | Because of my [problem], my ability to form and maintain **close relationships** with others, including those I live with, is impaired. | | | | | | | | 0 |

Total WSAS score = 0